Jc559 U.S. PTO
09/037690
03/10/98

130.1	Subclass	CLASSIFICATION

[redacted]

PATENT NUMBER
5919451
5919451

ATTACHMENT 9

SCANNED D wD Q.A. [illegible] | JUL 06 1999

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	424	130.1 ~~[illegible]~~	1644 ~~[illegible]~~	VANDERVEGT

FILED WITH: ☐ DISK (CRF) ☐ FICHE
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PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)						
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					
INTERNATIONAL CLASSIFICATION								
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☐ TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg.	Figs. Drwg.	Print Fig.	Total Claims	Print Claim for O.G.
	NONE	NONE	NONE	7	1

☐ a) The term of this patent subsequent to ________ (date) has been disclaimed.	E Pierre VanderVegt (Assistant Examiner) 12/4/98 (Date)	NOTICE OF ALLOWANCE MAILED: 12-7-98
☐ b) The term of this patent shall not extend beyond the expiration date of U.S Patent. No. ________	David Saunders DAVID SAUNDERS PRIMARY EXAMINER ART UNIT ~~182~~ 1644 — David Saunders (Primary Examiner) 12/4/98 (Date)	ISSUE FEE — Amount Due: $1210.00 — Date Paid: 3-3-99
☐ c) The terminal ____ months of this patent have been disclaimed.	________ (Legal Instruments Examiner) ____ (Date)	ISSUE BATCH NUMBER: M33

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(LABEL AREA) ISSUE FEE IN FILE

(FACE)

BRIEFED IN 1600

PATENT APPLICATION

09037690

INITIALS _____

PAR 239829

JC859 U.S. PTO
09/037690
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CONTENTS

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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION			
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FORMALITY REVIEW	RDS	65085 21	3/23/98

INDEX OF CLAIMS

✔ ..... Rejected
= ..... Allowed
– (Through numeral) Canceled
÷ ..... Restricted
N ..... Non-elected
I ..... Interference
A ..... Appeal
O ..... Objected

Claim Final	Claim Original	Date
1	1	11/25/97
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SEARCHED

Class	Sub.	Date	Exmr.
424	442 283.1 130.1 157.1 158.1	6/2/98	AJ
106	147.3 148.1 245		
426	89, 92 140 65		
530	~~384~~ 388.24 350.85 359.2		
UPDATED		11/24/98	AV

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
424	442 130.1 157.1 158.1	12/3/98	AV
106	124.1		
426	89 140 65		
530	388.2		

SEARCH NOTES
(INCLUDING SEARCH STRATEGY)

	Date	Exmr
APS DIALOG BIOTECH FEED/FOOD PARTICLE? ANTIBOD? CHOLECYSTOKININ LINOLEIC ACID FAT	6/2/98	AJ
APS DIALOG PROTEIN/MEDICINE INDEXES FEED/FOOD PARTICLE? ANTIBOD? ENDOGENOUS MOUTH	11/24/98	AV
CAROLYN PADEN GP 1700 EXR. 1761 FOOD ART	12/2/98	AV

(RIGHT OUTSIDE)

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

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01 FC:101 790.00 CH
02 FC:102 82.00 CH

PTO-1556
(5/87)

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/037,690	03/10/98	424	1644	960296.95297

APPLICANT

MARK E. COOK, MADISON, WI; DARIA L. JEROME, FRAZEE, MN.

CONTINUING DOMESTIC DATA********
VERIFIED THIS APPLN IS A CIP OF 08/694,785 07/22/96 PAT 5,725,873

371 (NAT'L STAGE) DATA********
VERIFIED

FOREIGN APPLICATIONS********
VERIFIED

FOREIGN FILING LICENSE GRANTED 03/27/98

Foreign Priority claimed 35 USC 119 (a-d) conditions met ☐yes ☐no ☐Met after Allowance Verified and Acknowledged _____ Examiner's Initials _____ Initials	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
	WI	0	10	4

ADDRESS

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TITLE

METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

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ABSTRACT OF THE DISCLOSURE

A method of improving the efficiency of an animal to convert feed into desirable body tissue involves feeding the animal feed particles having an inner core of nutrients and an outer layer containing a conjugated fatty acid or an antibody that can protect the animal from contacting diseases that can adversely affect the animal's ability to grow or efficiently convert its feed into body tissue.

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METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part application of application number 08/684,785, filed July 22, 1996, ~~which will issue as~~ US Patent No. 5,725,873 issued on March 10, 1998.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

BACKGROUND OF THE INVENTION

The present invention relates generally to the feeding of animals. More particularly, it relates to a method of improving the animal's growth or the efficiency of the animal to convert its feed into desirable body tissue (e.g. muscle) and compositions for use in the method.

It is known that healthy, disease-free animals grow faster or are more able to convert their feed efficiently into body tissue than sick or immune-challenged animals. Obviously, faster growth or a more efficient conversion of feed into desirable body tissue in an animal is both economically and ecologically important, especially in animals raised for food. For this, and other reasons, it is desirable to prevent animals from contacting diseases.

One approach to keeping animals healthy is to give the animals antibiotics. However, that approach is not desirable for animals raised for food because there can be antibiotic residues in the food.

Another approach to keeping animals healthy is to immunize the animals. This can be done by vaccinating the animals against specific diseases to produce an active immunization or by administering to the animals antibodies to produce a passive immunization.

In United States Patent Numbers 4,748,018 and 5,080,895, methods are disclosed for passively immunizing animals against intestinal diseases which could interfere with the animal's efficient conversion of feed. The patented methods basically comprise orally administering to said animals effective amounts of egg-derived materials containing avian antibodies which are obtained by immunizing egg-laying hens with specific antigens which will produce such antibodies, and obtaining the antibody containing material from eggs laid by the hen. In both patents, the antibody containing egg materials are reduced to powders and fed to the animals to be passively immunized.

BRIEF SUMMARY OF THE INVENTION

It is the primary object of the present invention to disclose a novel method to improve the animals growth or the efficiency of the animal to convert its feed into desirable body tissue.

Another object of the invention is to disclose an animal feed for animals for use in the inventive method.

The method of the present invention to improve the animals growth or the efficiency of the animal to convert its feed into desirable body tissue comprises orally administering to said animal feed particles having an inner core comprising primarily non-fat nutrients and, on an outer surface of the inner core, a safe and effective amount of an antibody that help protect the animal from disease or other antigens that can adversely affect the animal's growth or the efficiency of the animal to convert feed into desirable body tissue. The particles can alternatively be coated with another compound that improves the efficiency of the animal to convert feed into desirable body tissue.

The compositions of the present invention are animal feed particles having an inner core comprised of nutrients, and, on an outer surface of the inner core, a compound that improves the efficiency of the animal to convert feed into desirable body tissue.

The compositions of the present invention are conveniently made by first forming a nutrient mixture to

produce an inner core, and then depositing the compound on the outer surface of the core. Surprisingly, an antibody on the outer surface retains immunological activity and is not destroyed by antibody destroying factors, such as environmental conditions and intestinal proteases, even if the antibody is simply applied to the exterior of the pellet core without encapsulation in a protective fat layer.

In a preferred embodiment of the invention, antibodies are provided in solution or suspension in an aqueous or lipid carrier, although the antibodies can be applied directly to the pellet core without a carrier as, for example, a powder. The antibodies can be, but need not be, encapsulated in the lipid. The antibodies are obtained from the egg of a hen which has been injected with an antigen that results in the production by the hen of those antibodies.

Compositions of the present invention are superior to previously known animal feeds in which antibody-containing powders were mixed with nutrients, including fat, and then granulated or extruded, because the antibody-containing layer in the method of the present invention is applied to the core after the pelletization, extrusion, granulation or expansion process. As a result the antibodies in the outer layer of the compositions of the present invention are not degraded by elevated temperatures that can arise during pelletization, granulation, extrusion or expansion processes. The compositions of the present invention are also superior to prior art feeds. If the antibodies are mixed into an outer layer of fat, the fat helps protect the antibodies from stomach acid and intestinal enzymes. If the antibodies are not encapsulated in fat, they can be immediately released at high concentration into the gastrointestinal tract of the consuming animal and are not degraded upon ingestion.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Not applicable.

DETAILED DESCRIPTION OF THE INVENTION

In the preferred embodiment of the present invention, the animal feed particles comprise an extruded inner core

which contains primarily the desired non-fat materials, such as proteins and carbohydrates, and an outer layer of a compound that improves the efficiency of the animal to convert feed into desirable body tissue. The compound is preferably an antibody which can be optionally encapsulated in a lipid layer. Another compound that can be provided on the outer surface is a fatty acid that improves feed conversion efficiency. A preferred fatty acid is an 18-carbon conjugated diene. A most preferred fatty acid is conjugated linoleic acid (CLA). The outer layer also can contain other ingredients, such as oil-soluble vitamins and the inner core can, of course, also contain fat, if desired.

In the preferred practice of the method of invention, the animal feed is orally fed to the animal in an amount which will passively immunize the animal or otherwise enhance the efficiency of feed conversion by the animal.

The antibodies for use in the present invention are those which can alter physiological processes that adversely affect growth and feed efficiency. They can be antibodies that are against diseases or specific endogenous regulators of food intake and gastrointestinal motility. The antibodies are preferably derived from the eggs of hens which have been previously immunized to produce those antibodies as described in United States Patent Number 4,748,018 or 5,080,895. Especially preferred as the antibody-containing material are spray dried egg yolks and whole eggs. However, other non-egg derived antibody-containing materials may be used.

The free CLA isomers have been previously isolated from fried meats and described as anticarcinogens by Y. L. Ha et al., in Carcinogenesis 8(12):1881-1887 (1987). Since then, they have been found in some processed cheese products. Y.L. Ha, et al., J. Agric Food Chem. 37(1):75-81 (1987).

The free acid forms of the CLA may be prepared by isomerizng linoleic acid. The non-toxic salts of the free CLA may be made by reacting the free acids with a non-toxic base. Natural CLA may also be prepared from linoleic acid by the action of delta 12-cis, delta 11-transisomerase from a harmless microorganism such as the rumen bacterium *butyrivibrio fibrisolvens*. Harmless microorganisms in the

intestinal tracts of rats and other monogastric animals may also convert linoleic acid to CLA (Chin, S.F. et al., FASEB J. v. 6, abstract #2665 (1992).

The CLA obtained by the practice of the described methods contains one or more of the 9,11-octadecadienoic acids and/or the 10,12-octadecadienoic acids and active isomers thereof. It may be free or bound chemically through ester linkages. The CLA is heat stable and can be used as is, or dried and powdered. The CLA is readily converted into a non-toxic salt, such as the sodium or potassium salt, by reacting chemically equivalent amounts of the free acid with an alkali hydroxide at a pH of about 8 to 9.

CLA can be a mixture of isomers of 9,11- and 10,12-octadecadienoic acid (c9,c11; c9,t11; t9,c11; t9,t11; c10,c12; t10,c12; c10,t12; and t10,t12) that would form from isomerization of c9,c12-octadecadienoic acid. As a result of the isomerization, only four isomers (c9,c11; c9,t11; t10,c12; and c10,c12) would be expected. However, of the four isomers, c9,t11- and t10,c12 isomers are predominantly produced during the autoxidation or alkali-isomerization of c9,c12-linoleic acid due to the co-planar characteristics of 5 carbon atoms around a conjugated double-bond and spatial conflict of the resonance radical. The remaining two c,c-isomers are minor contributors.

The relatively higher distribution of the t,t-isomers of 9,11- or 10,12-octadecadienoic acid apparently results from the further stabilization of c9,t11- or t10,c12-geometric isomers, which is thermodynamically preferred, during an extended processing time or long aging period. Additionally, the t,t isomer of 9,11- or 10,12-octadecadienoic acid that was predominantly formed during the isomerization of linoleic acid geometrical isomers (t9,t12-, c9,t12- and t9,c12-octadecadienoic acid) may influence the final ratio of the isomers or the final CLA content in the samples.

Linoleic acid geometrical isomers also influence the distribution of minor contributors (c,c-isomers of 9,11- and 10,12-, t9,c11- and c11,t12-octadecadienoic acids). The 11,13-isomer might be produced as a minor product from

c9,c12-octadecadienoic acid or from its isomeric forms during processing.

The preferred inner core for the animal feed particles is an extrusion which contains a mixture of nutrients, such as grains, with or without added sugars, carbohydrates and/or proteins. The core will normally contain less than the desired total amount of the dietary fat for the animal because of the fat in the outer layer.

The fat for use in the outer layer can be any fat or lipid, which can be readily mixed with the antibody containing material to form a mixture, which contains the antibody therein and which can be readily sprayed or otherwise coated on the outer surface of the core. The antibody need not be directly on the surface of the inner core. Rather, one or more intermediate layers, comprising, for example, a binding agent, can be provided between the antibody and the core. Especially preferred are those fats which are solid at ambient temperatures and which will protect the antibodies from adverse environmental conditions and intestinal enzymes. Especially preferred as the fat is a mixture of tallow and CLA which increases feed efficiency.

Representative of other fats that can be used are the following:

Lard
Yellow Grease
Poultry Fat
Spent Restaurant Oil
Animal Oils
Vegetable Oils
Fish Oils
Oil Derivatives, i.e. lecithin
and
Mixtures thereof.

The practice of the present invention is further illustrated by the following examples:

Example 1

Preparation Of Antibodies.

An antigen, such as cholecystokinin peptide which produces cholecystokinin (CCK) antibodies, is injected intramuscularly into mature hens at a dose of about 50 μg to 1000 μg with a water-in-oil emulsion adjuvant. Samples of the whole eggs or yolks of eggs from the hens are assayed by known methods for CCK antibody content. When the CCK antibody titer reaches a maximum level, the whole eggs or yolks of eggs are collected and pooled, homogenized and spray dried to obtain a powder.

Example 2

Preparation Of Animal Feed Particles With Outer Layer Of Fat Containing Antibodies.

A CCK antibody-containing powder made by the process of Example 1 is mixed with tallow to form a blend in which the powder is substantially encapsulated by the fat. The fat mixture is then spray coated upon inner cores made by the pelletization, the granulation, the extrusion or the expansion of a plasticized mixture of nutrients, including carbohydrate, protein and water. The resulting animal feed particles have an inner core of nutrients and an outer layer of fat containing CCK antibodies.

Example 3

Animal Feeding Test.

Ducks are fed the animal feed of Example 2 and their biological responses are determined. It is found that the ducks receiving the animal feed of Example 2 demonstrate an improved body weight gain and a more efficient rate of feed conversion than control ducks.

Table 1 shows the results obtained in 14 day old ducks fed a control feed and an otherwise identical feed (BRAVO) having an outer antibody-containing layer.

TABLE 1

ABOVE BODY WEIGHT SUMMARY			
TREATMENT	14 day weight	27 day weight	14-27 day gain
Control	0.66 kg	2.03 kg	1.37 kg
Bravo	0.63 kg	1.96 kg	1.33 kg
TREATMENT	39 day weight	14-39 day gain	
Control	3.15 kg	2.49 kg	
Bravo	3.23 kg	2.60 kg	
FEED CONVERSION DATA			
TREATMENT	14-27 feed/bird	0-27 feed/bw*	14-17 feed/gain
Control	2.50 kg	0.558 kg	1.826 kg
Bravo	2.34 kg	0.541 kg	1.76 kg
TREATMENT	14-39 feed/bird	0-39 feed/bw*	14-39 feed/gain
Control	5.349 kg	0.781 kg	2.15 kg
Bravo	4.930 kg	0.695 kg	1.90 kg

* bw = body weight

Example 4

A CCK antibody-containing powder made by the process of Example 1 were mixed with tallow to form a blend in which the powder was substantially encapsulated by the fat. The fat mixture was then spray coated upon the inner cores, as described in Example 2, at the indicated antibody levels.

Chickens were fed the animal feed and their biological responses were determined. Table 2 shows the results obtained in chickens fed the coated feed pellets (crumbles) for three weeks. Also shown are the results obtained when

chickens were fed a standard feed mash containing the indicated amounts of the anti-CCK antibody.

In the course of the trial, both the rate of body gain and the feed efficiency were markedly higher in chickens fed the antibody-coated pellets than in those fed antibody-containing mash. Surprisingly, a superior increase is observed (relative to control feed) when the antibody is provided on pellets than as a component of mash.

Table 2

Treatment	Week 1 Body Wt	Week 0-1 Body Wt Gain	Feed/Bird 0-1 Consumed	Feed/Body Wt	Feed/Body Wt Gain
Week 1 (Mash)					
Control	132	93	124	0.938	1.344
0.075* Bravo	136	97	132	0.969	1.368
0.25 Bravo	138	98	131	0.947	1.338
0.75 Bravo	127	87	125	0.984	1.442
Week 2 (Crumbles)					
Control	152	112	143	0.942	1.287
0.075 Bravo	149	108	156	1.049	1.450
0.25 Bravo	155	114	141	0.969	1.315
0.75 Bravo	147	107	137	0.928	1.273
Week 2 (Mash)					
Control	311	272	384	1.237	1.421
0.075 Bravo	329	290	400	1.218	1.386
0.25 Bravo	323	283	396	1.226	1.401
0.75 Bravo	291	251	353	1.244	1.451
Week 2 (Crumbles)					
Control	366	325	477	1.243	1.390
0.075 Bravo	358	317	457	1.278	1.444
0.25 Bravo	358	317	470	1.314	1.485
0.75 Bravo	352	313	413	1.174	1.324
Week 3 (Mash)					
Control	624	584	823	1.316	1.406
0.075 Bravo	635	595	845	1.334	1.423
0.25 Bravo	608	568	835	1.375	1.473
0.75 Bravo	569	529	787	1.382	1.488
Week 3 (Crumbles)					
Control	683	642	936	1.373	1.461
0.075 Bravo	697	656	956	1.372	1.457
0.25 Bravo	699	659	971	1.395	1.482
0.75 Bravo	687	648	893	1.299	1.379

*grams of anti-CCK egg yolk per kilogram of feed.

Example 5

Ducks were fed a pelleted diet on which either 0.5% corn oil (control) or 0.5% conjugated linoleic acid was sprayed on the outer surface of the pellets. The coated pellets were fed to 14 day old ducks for 13 days. Feed conversion (feed

consumed per amount of gain) was determined from 14 to 27 days and 29 to 39 days of age.

Table 3

Treatment	14-27 day conversion	29-39 day conversion
Control	1.82	2.38
CLA	1.79	2.14

Feeding CLA from 14 to 27 days of age reduced feed conversion (pounds of feed per pound of gain). The effects of feeding pellets coated with CLA continued to have an effect even for the period between 29 to 39 days of age.

It will be apparent to those skilled in the art that the present invention can be used to prepare the animal feed for a wide variety of food animals or pets, including without limitation, ducks, chickens and turkeys.

It also will be readily apparent to those skilled in the art that a large number of changes and modifications can be made without departing from the spirit and scope of the present invention. Therefore, it is intended that the invention only be limited by the claims which follow.

CLAIMS

We claim:

1. A method to improve the growth of an animal or the efficiency of an animal to convert feed into desired body tissue, said method comprising feeding an animal an effective amount of animal feed particles comprising an inner core of nutrients and having an outer surface, and a layer comprising antibodies on the outer surface of the inner core,

said antibodies being antibodies that can passively immunize the animal against the adverse effects of an antigen which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue, wherein the method achieves superior growth or feed conversion than a second method wherein a comparable amount of the antibody is fed to the animal in an unpelleted form.

2. A method of Claim 1 in which the antibodies are derived from a chicken egg.

3. A method of Claim 1 in which the antibody layer comprises a fat.

4. A method of Claim 3 in which the fat is one which protects the antibodies from adverse environmental conditions.

5. A method of Claim 3 in which the fat is a mixture of a conjugated linoleic acid and another fat.

6. A method of Claim 1 in which the antibody is anti-cholecystokinin antibody.

7. A method to improve the growth of an animal or the efficiency of an animal to convert feed into desired body tissue, said method comprising feeding an animal an effective amount of animal feed particles comprising an inner core of nutrients and having an outer surface, and a layer comprising conjugated linoleic acid on the outer surface of the inner core.

8. A particulate animal feed comprising an inner core of nutrients, the core having an outer surface, and a layer of antibodies on the outer surface of the inner core.

9. A particulate animal feed as claimed in Claim 8 wherein the antibodies are anti-cholecystokinin antibodies.

10. A particulate animal feed comprising an inner core of nutrients, the core having an outer surface, and a layer of conjugated linoleic acid on the outer surface of the inner core.

PTO/SB/01 (6-95)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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2013/PTO
Rev. 6/95

U.S. Department of Commerce
Patent and Trademark Office

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

[x] Declaration Submitted with Initial Filing OR [ ] Declaration Submitted after Initial Filing

Attorney Docket Number	960296.94011
First Named Inventor	Mark E. Cook
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Method of Improving the Growth or the Efficiency of Feed Conversion of an Animal and Compositions for Use Therein

(Title of the Invention)

the specification of which

[x] is attached hereto

OR

[ ] was filed on (MM/DD/YY) [ ] as United States Application Number or PCT International

Application Number [ ] and was amended on (MM/DD/YY) [ ] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate or §386(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

[ ] Additional foreign applications numbers are listed on a supplemental priority sheet attached hereto:

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YY)	
		[ ] Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.

Burden Hour Statement: This form is estimated to take .4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.
OMMADI168284

Please type a plus sign (+) inside this box [+]

DECLARATION	Page 2

I hereby claim benefit under Title 35, United States Code §120 of any United States application(s), or §365(C) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application or PCT International application in the manner provided in the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YY)	Parent Patent Number *(if applicable)*
08/684,785		07/22/96	5,725,873

[ ] Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and all continuation and divisional applications based thereon, and to transact all business in the Patent and Trademark Office connected therewith:

[ ] Firm Name ______ Customer Number or label ______
OR
[X] List attorney(s) and/or agent(s) name and registration number below

Name	Registration Number	Name	Registration Number
Thad F. Kryshak	19,428	Gregory A. Nelson	30,577
Neil Hamilton	19,869	Keith M. Baxter	31,233
Thomas W. Ehrmann	20,374	John D. Franzini	31,356
Barry E. Sammons	25,608	Joseph W. Bain	34,290
J. Rodman Steele	25,931	Robert J. Sacco	35,667
Nicholas J. Seay	27,386	Jean C. Baker	35,433
George E. Haas	27,642	David G. Rysar	35,407
Michael J. McGovern	28,326	Bennett J. Berson	37,094
Carl R. Schwartz	29,437	Michael A. Jaskolski	37,551

18

[ ] Additional attorney(s) and/or agents named on a supplemental priority sheet attached hereto

Please direct all correspondence to [ ] Customer Number or label ______ OR [X] Fill in correspondence address below

Name	Bennett J. Berson
Address	Quarles & Brady
Address	P O Box 2113
City	Madison — State WI — Zip 53701-2113
Country	US — Telephone 608/251-5000 — Fax 608/251-9166

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Name of Sole or First Inventor: [ ] A petition has been filed for this unsigned inventor

Given Name	Mark	Middle Initial	E.	Family Name	Cook	Suffix e.g. Jr.			
Inventor's Signature						Date			
Residence: City	Madison	State	WI	Country	US	Citizenship	US		
Post Office Address	15 Kewaunee Court								
Post Office Address									
City	Madison	State	WI	Zip	53705	Country	US	Applicant Authority	

[ ] [x] Additional inventors are being named on supplemental sheet(s) attached hereto

09037690 . 030798

Please type a plus sign (+) inside this box [+]

DECLARATION	ADDITIONAL INVENTOR(S) Supplemental Sheet

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name	Middle	Family	Suffix
Daria	L.	Jerome	Sr.

Inventor's Signature | Date

Residence: City Middleton | State WI | Country US | Citizenship US

Post Office Address 5730 Highland Way, Apt. 204

Post Office Address

City Middleton | State WI | Zip 53562 | Country US | Authority

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name	Middle	Family	Suffix

Inventor's Signature | Date

Residence: City | State | Country | Citizenship

Post Office Address

Post Office Address

City | State | Zip | Country | Authority

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name	Middle	Family	Suffix

Inventor's Signature | Date

Residence: City | State | Country | Citizenship

Post Office Address

Post Office Address

City | State | Zip | Country | Authority

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name	Middle	Family	Suffix

Inventor's Signature | Date

Residence: City | State | Country | Citizenship

Post Office Address

Post Office Address

City | State | Zip | Country | Authority

☐ Additional inventors are being named on supplemental sheet(s) attached hereto

10/790.
10 2-82. A

PTO/SB/05 (1/98)
Approved for use through 9/30/00, OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Please type a plus sign (+) inside this box → +
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	960296.94011
First Inventor or Application Identifier	Merk E. Cook
Title	Method of Improving the Growth or the Efficiency of Feed
Express Mail Label No.	EE218789037US

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

1 [X] Fee transmittal Form (Submit an original and a duplicate for fee processing)

2 [X] Specification [Total Pages 13]
(preferred arrangement set forth below)
- Descriptive title of the invention
- Cross References to Related Applications
- Statement Regarding Fed Sponsored R&D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3 [ ] Drawing(s) (35 USC 113) [Total Sheets]

4. Oath or Declaration [Total Pages 3]
a. [ ] Newly executed (original or copy)
b. [ ] Copy from prior Application (37 CFR 1.63(d)) per continuation/divisional with Box 17 completed)
[Note Box 5 below]
i. [ ] DELETION OF INVENTOR(S)
Signed Statement attached deleting inventor(s) named in prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

5 [ ] Incorporation By Reference (useable if Box 4b is checked)
The entire disclosure of the prior application from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference herein.

6. [ ] Microfiche Computer Program *(Appendix)*

7. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
a. [ ] Computer readable Copy
b. [ ] Paper Copy (identical to computer copy)
c. [ ] Statement Verifying identity of above

ACCOMPANYING APPLICATION PARTS

8 [ ] Assignment Papers (cover sheet & documents)
9 [ ] 37 CFR 3.73(b) Statement [ ] Power of Attorney (where there is an assignee)
10 [ ] English Translation Document *(if applicable)*
11 [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
12 [ ] Preliminary Amendment
13 [ ] Return receipt postcard (MPEP 503) *(Should be specifically itemized)*
14 [ ] *Small Entity Statement(s) [ ] Statement filed in prior application, Status still proper and desired
15 [ ] Certified copy of priority Document(s) *(if foreign priority is claimed)*
16 [ ] Other:
* A new statement is required to pay small entity fees, except where one has been filed in a prior application and is being relied upon.

17. If a CONTINUING APPLICATION, *check appropriate box and supply the requisite information:*
[ ] Continuation [ ] Divisional [X] Continuation-in-part (CIP) of prior application no: 08/884,785
Prior application Information: Examiner: F. Vandervegt Group/Art Unit: 1816

18. CORRESPONDENCE ADDRESS

[ ] Customer Number or Bar Code Label [redacted] or [X] Correspondence address below

NAME	Bennett J. Berson
	Querles & Bredy
ADDRESS	P O Box 2113
CITY	Madison STATE WI ZIP CODE 53701-2113
COUNTRY	US TELEPHONE 608/251-5000 FAX 608/251-9166

Name (Print/Type)	Bennett J. Berson	Registration No. (Attorney/Agent)	37,094
Signature	[signature]	Date	March 10, 1998

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231. CBMAD1156295

EXPRESS MAIL LABEL NO. EE218781 5

PTO/SB/17 (11/98)
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
oved for use through 9/30/98. OMB 0651-0032

FEE TRANSMITTAL

Patent fees are subject to annual revision on October 1.
These are the fees effective October 1, 1997.
Small Entity payments must be supported by a small entity statement
otherwise large entity fees must be paid, See Forms PTO/SB/09-12

TOTAL AMOUNT OF PAYMENT | $ 872.00

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Mark E.Cook
Group Art Unit	1816
Examiner Neme	
Attorney Docket Number	960296.94011

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

[ ] Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. [ ] Payment Enclosed:
[ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fees effective 10/01/97)

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	790.00
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)790.00

2. CLAIMS

	Extra		Fee from below	Fee Paid
Total Claims 10	-20**=		X =	
Independent Claims 4	-3**=	1	X 62 =	62.00
Multiple Dependent Claims			=	

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	22	203	11	Claims in excess of 20
102	82	202	41	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim
109	80	209	40	**Reissue independent claims over original patent
110	22	210	11	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)62.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)		Fee
105	130	205	65	Surcharge - late filing fee or oath	
127	* 50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	*920	112	*920	Requesting publication of SIR prior to Examiner action	
113	*1,840	113	*1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	950	217	475	Extension for reply within third month	
118	1,510	218	755	Extension for reply within fourth month	
128	2,060	228	1,030	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,320	241	660	Petition to revive unintentionally abandoned application	
142	1,320	242	660	Utility issue fee (or reissue)	
143	450	243	225	Design issue fee	
144	670	244	335	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	125	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
148	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify) _____

Other fee (specify) _____

SUBTOTAL (3) ($)

* Reduced by Basic Filing Fee Paid

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	Bennett J. Berson			Reg. Number	37,094
Signature		Date	March 10, 1998	Deposit Account User ID	

QBMAD\156298

Firstar Plaza
P.O. Box 2113
Madison, Wisconsin 53701-2113
608/251-5000
FAX 608/251-9166
http://www.quarles.com

Attorneys at Law in
Milwaukee and Madison, Wisconsin
West Palm Beach and Naples, Florida
Phoenix, Arizona

Quarles & Brady

March 10, 1998

Assistant Commissioner of Patents
Box Patent Application
Washington DC 20231

Re: Filing New Patent Application

Dear Sir:

Enclosed for filing please find a new patent application entitled: METHOD OF IMPROVING THE GROWTH OF THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

by Mark E. Cook
Daria L. Jerome

The undersigned hereby certifies that this document is being deposited with the United States Postal Service today, March 10, 1998, by the "Express Mail" service, utilizing Express Mail label number EE218789037US, addressed to: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

Please indicate receipt of this application by returning the attached postcard with the official Patent and Trademark Office receipt and serial number stamped thereon.

Respectfully submitted,

Daria Jerome

QBMAD\156301

09037690.031098

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/037,490	03/10/98	COOK	M 960296.94011

0232/0327

BENNETT J. BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

NOT ASSIGNED

1615

DATE MAILED: 03/27/98

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ _____.

☐ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $ _____ to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☐ 2. Additional claim fees of $ _____, including any multiple dependent claim fees, are required.

$ _____ for _____ independent claims over 3.

$ _____ for _____ dependent claims over 20.

$ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☐ is missing or unexecuted.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☒ 4. The signature(s) to the oath or declaration is/are by a person other than Inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.

A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application does not comply with the Sequence Rules.
See attached "Notice to Comply with Sequence Rules 37 CFR 1.821-1.825."

☐ 9. OTHER: _____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

FORM PTO-1533 (REV-3-97)

Receipt

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

Date of Signature and Deposit: April 30, 1998

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. Cook
Daria L. Jerome

Date: April 30, 1998

Serial No.: 09/037,690

Group Art Unit: 1615

Filed: 03/10/98

Examiner:

For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

File No.: 960296.94011 (now 960296.95297)

REQUEST FOR CORRECTED FILING RECEIPT

Assistant Commissioner For Patents
Application Processing Division
Customers Correction Branch
Washington DC 20231

Dear Sir:

Errors were noted in the Filing Receipt received in connection with the above-noted patent application.

The Filing Receipt lists only one of the two named inventors. The name of inventor Daria L. Jerome was omitted. Both inventors were named on the Declaration filed with the application.

In the title, the word "Improving" is spelled incorrectly.

The Filing Receipt indicates that no filing fee was received. However, the PTO was authorized to charge the $872.00 filing fee to our firm deposit account according to the fee transmittal form submitted with the application. It

is believed that the fee was paid since the Notice of File Missing Parts of Application does not request any additional filing fee.

A copy of the Filing Receipt with the changes noted thereon is attached.

A corrected Filing Receipt is respectfully requested.

Respectfully submitted,

Bennett J. Gerson
Reg. No. 37,094
Attorney for Applicants
QUARLES & BRADY
P.O. Box 2113
Madison, WI 53701-2113
(608) 251-5000

QBMAD\160031

EXPRESS MAIL LABEL NO. _____

PTO/SB/17 (1/98)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL

Patent fees are subject to annual revision on October 1.
These are the fees effective October 1, 1997.
Small entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12

TOTAL AMOUNT OF PAYMENT | $

Complete if Known	
Application Number	09/037,690
Filing Date	03/10/98
First Named Inventor	Mark E.Cook
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	960296.94011

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17 [ ] Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. [ ] Payment Enclosed: [ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fees effective 10/01/97)

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)

2. CLAIMS

	Extra		Fee from below	Fee Paid
Total Claims		-20**=	X	=
Independent Claims		-3**=	X	=
Multiple Dependent Claims				=

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	22	203	11	Claims in excess of 20
102	82	202	41	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim
109	80	209	40	**Reissue independent claims over original patent
110	22	210	11	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	*920	112	*920	Requesting publication of SIR prior to Examiner action	
113	*1,840	113	*1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	950	217	475	Extension for reply within third month	
118	1,510	218	755	Extension for reply within fourth month	
128	2,060	228	1,030	Extension for reply within fifth month	
119	310	218	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,320	241	660	Petition to revive unintentionally abandoned application	
142	1,320	242	660	Utility issue fee (or reissue)	
143	450	243	225	Design issue fee	
144	670	244	335	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
145	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
149	790	248	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify) _____

Other fee (specify) _____

SUBTOTAL (3) ($)

* Reduced by Basic Filing Fee Paid

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	Bennett J. Berson			Reg. Number	37,094
Signature		Date	April 30, 1998	Deposit Account User ID	

GBMAD\180035 (now 960296.94011)

PTO-103X
(Rev. 8-95)

FILING RECEIPT

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/037,690	03/10/98	1615	$0.00	960296.94011	0	10	4

$872.00

BENNETT J.BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

MARK E. COOK, MADISON, WI. Daria L. Jerma, Middleton, WI

CONTINUING DATA AS CLAIMED BY APPLICANT-
THIS APPLN IS A CIP OF 08/684,785 07/22/96 PAT 5,725,873

FOREIGN FILING LICENSE GRANTED 03/27/98
TITLE
METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

PRELIMINARY CLASS: 424

(see reverse)

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/037,690	03/10/98	424	1644	960296.94011

APPLICANT

MARK E. COOK, MADISON, WI; DARIA L. JEROME, FRAZEE, MN.

CONTINUING DOMESTIC DATA********
VERIFIED THIS APPLN IS A CIP OF 08/684,785 07/22/96 PAT. 5,725,873

371 (NAT'L STAGE) DATA********
VERIFIED NONE

FOREIGN APPLICATIONS********
VERIFIED NONE

FOREIGN FILING LICENSE GRANTED 03/27/98

Foreign Priority claimed 35 USC 119 (a-d) conditions met	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐yes ☑no ☐Met after Allowance Verified and Acknowledged Examiner's Initials _____ Initials	WI	0	10	4

ADDRESS

BENNETT J.BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

TITLE

METHOD OF IMPROOVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
$1,002	No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/037,690	03/10/98	COOK	M	960296.94011

HM11/0604

BENNETT J.BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

EXAMINER	
VANDERVEGT,F	
ART UNIT	**PAPER NUMBER**
1644	3

DATE MAILED: 06/04/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/91)

1- File Copy

Office Action Summary	Application No. 09/037,690	Applicant(s) Cook et al
	Examiner F. Pierre VanderVegt	Group Art Unit 1644

☐ Responsive to communication(s) filed on _____.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-10* _____ *is*/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10* _____ *is*/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(e)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

This application is a continuation of application S.N. 08/684,785. The status of the parent application should be amended at page 1 of the specification.

Claims 1-10 are pending in this application.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 8 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,726,873 (A on form PTO-892). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the '873 patent is drawn to a particulate animal feed comprising an inner core of nutrients, specifically incorporating carbohydrates and protein, while the instant claims are drawn merely to the inner core of nutrients. The '873 further comprises an outer layer comprising anti-cholecystokinin antibodies, the same as instant claim 9, which is a specific embodiment of instant claim 8. The instantly recited feature of an "outer surface" is merely an inherent property of any solid particle and carries no patentable distinction over the invention of the '873 patent. The instant claims 8 and 9 clearly encompass the invention of claim 1 of the '873 patent and are not patentably distinct therefrom.

Claim Rejections - 35 USC § 112

3. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing animals with antibody to cholecystokinin (CCK), does not reasonably provide enablement for passively immunizing an animal against antigens which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification discloses immunization of hens with CCK and feeding the antibodies to CCK obtained from their eggs to ducks. CCK is a natural peptide secreted by the mucosa of the upper intestine which stimulates contraction of the gall bladder and secretion of pancreatic enzymes which are desirable events in the digestion process. The specification further does not provide guidance how to determine antigens which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue. Given the nature of the invention, which is to enhance the digestive process, it would require undue experimentation on the part of a skilled artisan to determine which other antigens that are active in digestive processes would be suitable as targets for antibodies which are administered orally by the method of the present invention. Further, the specification provides no guidance as to which antigens to which the animal is exposed from external sources would be suitable immunogens for use in the present invention.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the nature of the invention, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(C) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5, 7-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al, U.S. Patent 5,428,072 (B), in view of Tokoro et al, U. S. Patent 5,080,895 (C), Albright et al (U) and Ludington et al, U.S. Patent 3,119,691 (D).

The '072 patent teaches a method and composition to improve the efficiency of feed conversion in an animal comprising adding to the feed of the animal an effective amount of conjugated linoleic acid (CLA; Abstract and column 1, lines 54-68 in particular). The '072 patent further shows that chicks fed the CLA as a supplement required less standard poultry feed for equivalent weight gain to controls receiving unsupplemented standard poultry feed (Example 1 in particular). The '072 patent also teaches that the CLA had to be mixed with the feed on a daily basis (Examples 2 & 3 in particular). The '072 patent does not teach antibodies encapsulated in fat as a coating for feed particles. The '895 patent teaches a method for immunizing female chickens with an antigen, such as a pathogenic bacteria, and obtaining an antibody preparation to said antigen from the eggs of the chickens which is processed into a dry powder (Example 1 in particular. The '895 patent further teaches that this preparation is useful for protecting animals from the pathogen used to immunize the chicken and exemplifies this by feeding the preparation to neonatal pigs (Example III in particular). The combination of references does not teach encapsulation of the antibody or CLA in protective fat as a coating for food particles. Albright et al teaches the encapsulation of vitamin A, another dietary supplement, in a lipid composition which protects the vitamin A from mineral catalyzed degradation and hydrolysis for extended periods of time (see entire document). The combination of references does not teach coating of feed particles. The '691 patent teaches coating animal food particles by spraying with fat which

melts when warmed but solidifies at room temperature (column 4, line 66 through column 5, line 22 in particular). The '691 patent also teaches that said fat may have a powder dispersed in it (column 5, lines 31-37 in particular). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the anti-pathogen antibodies of the '895 patent and the feed conversion enhancing CLA of the '072 patent with the protective fat coating taught by Albright et al and spray the mixture as a coating on an animal feed product. One would have been motivated to combine these teachings with a reasonable expectation of success by the desire to protect animals, such as a commercial livestock, from specific pathogens using easily produced and prepared antibodies to the pathogen and protect the antibody molecules from degradative forces during storage using fat encapsulation. One would have been further motivated to add the CLA in order to reduce the amount of feed required by the animals to thrive and to apply the mixture directly to the food particles as a coating in order to control the amount of supplement delivered to the animals relative to the amount of food given, without having to mix each time the animals are fed and non-intake of the supplements due to settling of powders out of pelletized foods. Motivation to provide these supplements as a coating, rather than admixed directly with the nutrients of the food pellet, is provided by the fact that some animal feed products must be heated during processing to temperatures which would destroy the antibodies.

Conclusion

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

6. The Group and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.

7. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm ET. a message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

June 3, 1998
F. Pierre VanderVegt, Ph.D.
Patent Examiner
Art Unit 1644

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644

Notice of References Cited

Application No.	Applicant(s)		
09/037,690	Cook et al		
Examiner	Group Art Unit	Page 1 of 1	
F. Pierre VanderVegt	1644		

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,725,873	3/10/98	Cook et al	424	442
B	5,428,072	6/27/95	Cook et al	514	460
C	5,080,895	1/14/92	Tokoro	424	85.8
D	3,119,691	1/28/64	Ludington et al	99	2
E					
F					
G					
H					
I					
J					
K					
L					
M					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
N						
O						
P						
Q						
R						
S						
T						

NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
U	Albright, RB et al. Drug. Dev. Ind. Pharm. 20(12):2035-2039.	7/94
V		
W		
X		

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Signature and Deposit: May 27, 1998

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. Cook
Daria L. Jerome

Date: May 27, 1998

Serial No.: 09/037,690

Group Art Unit: 1615

Filed: 03/10/98

Examiner:

For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

File No.: 960296.94011
(now 960296.95297)

RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION
FILING DATE GRANTED

Assistant Commissioner for Patents
Attention: Box Missing Parts
Washington, D.C. 20231

Dear Sir:

In a Notice to File Missing Parts of Application mailed March 27, 1998, the applicants were given two months from the mailing date to file all required items and pay the required fees.

The Notice indicated that the signature to the Declaration was by a person other than the inventor or other qualified person. In fact, the Declaration submitted with the application was unsigned. It is believed that the Notice to File Missing Parts is in error in that an improper box on the form was checked.

In any event, the applicants submit herewith Declarations of inventors Mark E. Cook and Daria L. Jerome, executed in counterparts.

A surcharge, set forth in 37 C.F.R. §1.16(e) believed to be $130, is due in connection with this submission. Please charge the fee to Deposit Account No. 17-0055. No other fee is believed due in connection with this response.

It is believed that all missing parts are now on file.

Respectfully submitted,

Bennett J. Jerson
Reg. No. 37,094
Attorney for Applicants
QUARLES & BRADY
P.O. Box 2113
Madison, WI 53701-2113

(608) 251-5000

QBMAD\161987

Please type a plus sign (+) inside this box [+]

PTO/SB/01 (6-95)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PTO/SB/01D
Rev. 6/95

U.S. Department of Commerce
Patent and Trademark Office

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

[ ] Declaration Submitted with Initial Filing OR [X] Declaration Submitted after Initial Filing

Attorney Docket Number	960296.94011
First Named Inventor	Mark E. Cook
COMPLETE IF KNOWN	
Application Number	09/037,690
Filing Date	03/10/98
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Method of Improving the Growth or the Efficiency of Feed Conversion of an Animel end Compositions for Use Therein

(Title of the Invention)

the specification of which

[ ] is attached hereto

OR

[X] was filed on (MM/DD/YY) 03/10/98 as United States Application Number or PCT International

Application Number 09/037,690 and was amended on (MM/DD/YY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

[ ] Additional foreign applications numbers are listed on a supplemental priority sheet attached hereto:

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YY)	
		[ ] Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.

Please type a plus sign (+) inside this box [+]

DECLARATION

I hereby claim benefit under Title 35, United States Code §120 of any United States application(s), or §365(C) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided in the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YY)	Parent Patent Number (If applicable)
08/884,785		07/22/96	5,725,873

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and all continuation and divisional applications based thereon, and to transact all business in the Patent and Trademark Office connected therewith:

☐ Firm Name _____ Customer Number or label _____

OR

☒ List attorney(s) and/or agent(s) name and registration number below

Name	Registration Number	Name	Registration Number
Thad F. Kryshak	19,428	Gregory A. Nelson	30,577
Neil Hamilton	19,869	Keith M. Baxter	31,233
Thomas W. Ehmann	20,374	John D. Franzini	31,358
Barry E. Semmons	25,608	Joseph W. Bein	34,290
J. Rodman Steele	25,931	Robert J. Secco	36,667
Nicholas J. Seay	27,386	Jean C. Baker	35,433
George E. Haas	27,842	David G. Ryser	35,407
Michael J. McGovern	28,326	Bernard J. Berson	37,094
Carl R. Schwertz	29,437	Michael A. Jaskolski	37,551

☐ Additional attorney(s) and/or agents named on a supplemental priority sheet attached hereto

Please direct all correspondence to ☐ Customer Number or label _____ OR ☒ Fill in correspondence address below

Name: Bennett J. Berson

Address: Quarles & Brady

Address: P O Box 2113

City: Madison State: WI Zip: 53701-2113

Country: US Telephone: 608/251-5000 Fax: 608/251-9166

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name: Mark | Middle: E. | Family: Cook | Suffix: Jr.

Inventor's Signature: Mark E. Cook | Date: 4/30/98

Residence: City: Madison | State: WI | Country: US | Citizenship: US

Post Office Address: 15 Kewaunee Court

Post Office Address: _____

City: Madison | State: WI | Zip: 53705 | Country: US | Additional

☐ Additional inventors are being named on supplemental sheet(s) attached hereto

Please type a plus sign (+) inside this box [+]

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:

A petition has been filed for this unsigned inventor

Given Name	Middle	Family Name	Suffix
Darla	L.	Jerome	

Inventor's Signature | Date

Residence: City | State | Country: US | Citizenship: US

Post Office Address

Post Office Address

City | State | Zip | Country: US | Additional

Name of Additional Joint Inventor, if any:

A petition has been filed for this unsigned inventor

Given Name	Middle	Family Name	Suffix

Inventor's Signature | Date

Residence: City | State | Country | Citizenship

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Please type a plus sign (+) inside this box [+]

Approved for use through 9/30/98. PTO/SB/01 (6-95)
OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

U.S. Department of Commerce
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION

[ ] Declaration Submitted with Initial Filing OR [X] Declaration Submitted after Initial Filing

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Filing Dete	03/10/98
Group Art Unit	
Examiner Nema	

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Method of Improving the Growth or the Efficiency of Feed Conversion of an Animal and Compositions for Use Therein

the specification of which *(Title of the Invention)*

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OR
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Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
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			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

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DECLARATION

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U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YY)	Parent Patent Number *(if applicable)*
08/684,785		07/22/96	6,725,873

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As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and all continuation and divisional applications based thereon, and to transact all business in the Patent and Trademark Office connected therewith:

☐ Firm Name OR [X] List attorney(s) and/or agent(s) name and registration number below

Customer Number or label

Name	Registration Number	Name	Registration Number
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Barry E. Sammons	25,606	Joseph W. Bain	34,290
J. Rodman Steele	26,931	Robert J. Secco	35,887
Nicholas J. Seay	27,386	Jean C. Baker	35,433
George E. Hess	27,642	David G. Ryser	35,407
Michael J. McGovern	28,326	Bennett J. Barson	37,094
Carl R. Schwartz	29,437	Michael A. Jaskolski	37,551

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Please direct all correspondence to ☐ Customer Number or label OR [X] Fill in correspondence address below

Name	Bennett J. Barson
Address	Quarles & Brady
Address	P O Box 2113
City	Madison
State	WI
Zip	53701-2113
Country	US
Telephone	608/251-5000
Fax	608/251-9166

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Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name	Middle Initial	Family Name	Suffix (e.g., Jr.)
Mark	E.	Cook	

Inventor's Signature: Date:

Residence: City	State	Country	Citizenship
Madison	WI	US	US

Post Office Address: 15 Kaweunee Court

Post Office Address:

City	State	Zip	Country	Additional Inventors
Madison	WI	53705	US	

☐ Additional inventors are being named on supplemental sheet(s) attached hereto

Please type a plus sign (+) inside this box [+]

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name: Daria | Middle: L. | Family: Jerome | Suffix:

Inventor's Signature: Daria L Jerome | Date: 4-21-98

Residence: City: Frazee | State: MN | Country: US | Citizenship: US

Post Office Address: P.O. Box 1462

Post Office Address:

City: Detroit Lakes | State: MN | Zip: 56502 | Country: US | Assignee

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name: | Middle: | Family: | Suffix:

Inventor's Signature: | Date:

Residence: City: | State: | Country: | Citizenship:

Post Office Address:

Post Office Address:

City: | State: | Zip: | Country: | Assignee

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name: | Middle: | Family: | Suffix:

Inventor's Signature: | Date:

Residence: City: | State: | Country: | Citizenship:

Post Office Address:

Post Office Address:

City: | State: | Zip: | Country: | Assignee

Name of Additional Joint Inventor, if any: | A petition has been filed for this unsigned inventor

Given Name: | Middle: | Family: | Suffix:

Inventor's Signature: | Date:

Residence: City: | State: | Country: | Citizenship:

Post Office Address:

Post Office Address:

City: | State: | Zip: | Country: | Assignee

☐ Additional inventors are being named on supplemental sheet(s) attached hereto

EXPRESS MAIL LABEL NO. ____________

1615

PTO/SB/17 (1/98)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL

JUN - 1 1998

Patent fees are subject to annual revision on October 1.
These are the fees effective October 1, 1997.
Small Entity payments must be supported by a small entity statement otherwise large entity fees must be paid, See Forms PTO/SB/09-12

Complete if Known	
Application Number	09/037,690
Filing Date	03/10/98
First Named Inventor	Mark E. Cook
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	960296.94011 (now 960296.95297)

TOTAL AMOUNT OF PAYMENT $ 130.00

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

[ ] Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. [ ] Payment Enclosed:

[ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fees effective 10/01/97)

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)

2. CLAIMS

			Extra		Fee from below		Fee Paid
Total Claims		-20** =		X		=	
Independent Claims		-3** =		X		=	
Multiple Dependent Claims						=	

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
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104	270	204	135	Multiple dependent claim
109	80	209	40	**Reissue independent claims over original patent
110	22	210	11	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee
105	130	205	65	Surcharge - late filing fee or oath	130.00
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	*920	112	*920	Requesting publication of SIR prior to Examiner action	
113	*1,840	113	*1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
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128	2,060	228	1,030	Extension for reply within fifth month	
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126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
149	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify) ____________

Other fee (specify) ____________

SUBTOTAL (3) ($)130.00

* Reduced by Basic Filing Fee Paid

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	Bennett J. Berson			Reg. Number	37,094
Signature	[signature]	Date	May 27, 1998	Deposit Account User ID	

QBMAD\161991 (now 960296.95297)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY OF COMMERCE AND
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

NOTICE OF FILING/CLAIM FEE(S) DUE

TO ENSURE PROPER CREDIT OF FEES, PLEASE RETURN A COPY OF THIS FEE CALCULATION SHEET WITH YOUR RESPONSE.

APPLICATION NUMBER: 09/037690

Total Fee Calculation

	Fee Code Sm./Lg.	Total # Claims	Number Extra	X	Fee Sm. Entity	Fee Lg. Entity	= Total
Basic Filing Fee	201/101					✓	
Total Claims >20	203/103	____	-20 = ____	X	____	____	____
Independent Claims >3	202/102	____	-3 = ____	X	____	____	____
Mult. Dep Claim Present	204/104				____	____	____
Surcharge	205/105				____	____	____
English Translation	139				____	____	130.00
							____

TOTAL FEE CALCULATION ____

Fees due upon filing the application:

Total Filing Fees Due = $ _____

Less Filing Fees Submitted - $ _____

BALANCE DUE = $ 130.00

Melinda A
Office of Initial Patent Examination

Unsigned Declaration

FORM OIPE-RAM-01 (Rev. 5/97)

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/037,820	03/10/98 COOK	M	960296.94011

BENNETT J. BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

2837/0327

NOT ASSIGNED

1615

DATE MAILED: 03/27/98

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of Items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ ***small entity (statement filed)*** ☐ ***non-small entity is $ _____***

☐ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $ _____ to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☐ 2. Additional claim fees of $ _____ including any multiple dependent claim fees, are required.

$ _____ for _____ independent claims over 3

$ _____ for _____ dependent claims over 20.

$ _____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☐ 3. The oath or declaration:
- ☐ is missing or unexecuted.
- ☐ does not cover the newly submitted items.
- ☐ does not identify the application to which it applies.
- ☐ does not include the city and state or foreign country of applicant's residence.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.

A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application does not comply with the Sequence Rules. *See attached Notice to Comply with Sequence Rules 37 CFR 1.821-1.825.*

☐ 9. OTHER:

Direct the reply and any questions about this notice to "Attention: Box Missing Parts"

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE

FORM PTO-1693 (REV 8-97)

GP1644

#5
S.Q.J
10/29/98

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. Cook et al. Date: June 9, 1998

Serial No.: 09/037,690 Group Art Unit: 1644

Filed: March 10, 1998 Examiner: F. VanderVegt

File No.: 960296.95297 (formerly 960296.94011)

For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner For Patents
Box Non-Fee
Washington DC 20231

Dear Sir:

Enclosed is a completed form PTO-1449 listing documents which the applicants in the above-identified application wish to bring to the attention of the Examiner for consideration in connection with the examination on the merits of this application.

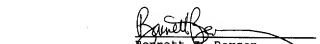
This application is a continuation-in-part of U.S. Application Serial No. 08/684,785, filed July 22, 1996, now U.S. Patent No. 5,725,873. The documents listed on the Form 1449 were previously cited by or submitted to the Office in U.S. Application No. 08/684,785. Pursuant to 1.98(d), copies of documents that were earlier cited by or submitted to the Office in a prior application are not included herein.

The Applicants note that in an Office Action mailed June 4, 1998, the Examiner cited Cook *et al.* (U.S. Patent No. 5,428,072), Tokoro (U.S. Patent No. 5,080,895), Ludington *et al.* (U.S. Patent No. 3,119,691), and Albright et al., Drug Dev. Ind. Pharm. 20(12):2035-2039 (1994), all of record in U.S. Patent No. 5,725,873, which was also cited by the

Examiner. These citations are not repeated on the attached PTO-1449.

No additional fee is believed due in connection with the submission of this Information Disclosure Statement, because it is being submitted within three months of the filing date. However, should any fee be due, please charge the fee to Deposit Account No. 17-0055.

Respectfully submitted,



Kennett S. Berson
Reg. No. 37,094
Attorney for Applicant
QUARLES & BRADY
P.O. Box 2113
Madison, WI 53701-2113
(608)251-5000

QBMAD\160499

Form PTO-1449 (Rev. 2-98)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.	SERIAL NO.
960296.95297	09/037,690

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Mark E. Cook et al.

FILING DATE: 3/10/98 GROUP: 1644

U.S. PATENT DOCUMENTS

* EXAMINER'S INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
RV		4,357,272	11/02/82	Polson	260	112	03/15/79
|		4,550,019	10/29/85	Polson	424	85	07/16/82
|		4,748,018	5/31/88	Stolle et al.	424	87	08/19/84

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
RV		0241441A1	10/14/87	EPO	~~C12~~	~~1/04~~	X	
|		WO9421284	09/29/94	PCT	~~A61~~	~~37/54~~	X	
|		0428483A2	05/08/91	EPO	~~A61~~	~~9/16~~	X	
|		WO9101803	02/21/91	PCT	~~B01~~	~~13/04~~	X	
|		0231817A2	08/12/87	EPO	~~A23~~	~~1/08~~		X
|		0707798A1	04/24/98	PCT	~~A23~~	~~1/00~~		X
|		0558883A1	08/25/93	PCT	~~A23~~	~~1/10~~	X	
|		WO9804933	02/22/98	PCT	~~A61~~	~~39/395~~	X	
|		WO9822028	07/25/96	PCT	~~A23~~	~~1/00~~	X	

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER: D. R. Shukla DATE CONSIDERED: 11/24/98

* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. GBMAD1\162996

EXPRESS MAIL LABEL NO. _____

PTO/SB/17 (1/98)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL

Patent fees are subject to annual revision on October 1, 1997. These are the fees effective October 1, 1997.
Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12

TOTAL AMOUNT OF $

Complete If Known	
Application Number	09/037,690
Filing Date	3/10/98
First Named Inventor	Mark E. Cook
Group Art Unit	1644
Examiner Name	F. Pierre VanderVegt
Attorney Docket	960296.95297

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17 [ ] Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. [ ] Payment Enclosed: [ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fees effective 10/01/97)

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 0

2. CLAIMS

		Extra		Fee from below		Fee Paid
Total Claims		-20**=		X	=	
Independent Claims		-3**=		X	=	
Multiple Dependent Claims					=	

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
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102	82	202	41	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim
109	80	209	40	**Reissue independent claims over original patent
110	22	210	11	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920	112	920	Requesting publication of SIR prior to Examiner action	
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138	1,510	138	1,510	Petition to institute a public use proceeding	
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122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
149	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify) Information Disclosure Statement 0

Other fee (specify) _____

SUBTOTAL (3) ($) 0

* Reduced by Basic Filing Fee Paid

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	Bennett J. Berson			Reg. Number	37,094
Signature		Date	June 9, 1998	Deposit Account User ID	

DBMAD\1631114

GAU 1644

PATENT

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231

Date of Signature and Deposit October 5, 1998

Bennett J. Berson, Reg. No. 37,094

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#6 4.9.99 10/29/98

Applicants: Cook/Jerome

Serial No.: 09/037,690

Filed: 03/10/98

OIPE OCT 09 1998 PATENT & TRADEMARK OFFICE

Date: October 5, 1998

Examiner: F. Vandervegt

Art Unit: 1644

For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

File No.: 960296.94011 (now 960296.95297)

PETITION AND FEE FOR EXTENSION OF TIME
(37 CFR 1.136(a))

Assistant Commissioner For Patents
Washington, D.C. 20231

Sir:

Applicant hereby petitions the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated 06/04/98 for one(1) month(s) from 09/04/98 to 10/04/98.

Applicant is
[] a small entity, a verified statement for which:
[] is attached.
[] was filed previously.
[X] other than a small entity.

Extension:	Months	Fee for Non-Small Entity	Fee for Small Entity	
[X]	one month	$110.00	$55.00	
[ ]	two months	$400.00	$200.00	
[ ]	three months	$950.00	$475.00	
[ ]	four months	$1510.00	$755.00	
[ ]	five months	$2060.00	$1030.00	Fee $110.00

Please charge the above-identified fee and any additional fee due in this application to Deposit Account No. 17-0055.

A response to the Office Action
[X] is filed herewith.
[ ] has been filed.

Respectfully submitted,

By: _____
Bennett J. Berson
Reg. No. 37,094

10/13/1998 AIBRAHIM 00000146 170055 09037690

01 FC:115 110.00 CH

Quarles and Brady
P O Box 2113
Madison, WI 53701-2113
(608)251-5000

QBMAD\171850

RECEIVED OCT 13 1998 GROUP 1600

EXPRESS MAIL LABEL NO. _____

PTO/SB/17 (1/98)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL

OCT 09 1998

Patent fees are subject to annual revision on October 1.
These are the fees effective October 1, 1998.
Small Entity payments must be supported by a small entity statement,
otherwise large entity fees must be paid. See Forma PTO/SB/09-12

TOTAL AMOUNT OF	$192.00

Complete If Known

Application Number	09/037,690
Filing Date	3/10/98
First Named Inventor	Mark E. Cook
Group Art Unit	1644
Examiner Name	F. Pierre VanderVegt
Attorney Docket	960296.95297

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Deposit Account Name: Quarles & Brady

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2. [ ] Payment Enclosed: [ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fees effective 10/01/97)

1. FILING FEE

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108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($0)

2. CLAIMS

			Extra		Fee from below		Fee Paid
Total Claims	10	-20**=		X		=	
Independent Claims	5(4)	-3**=	1	X	82	=	
Multiple Dependent Claims						=	

** or number previously paid, if greater, For reissues see below

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110	22	210	11	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($82.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)		Fee
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140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,320	241	660	Petition to revive unintentionally abandoned application	
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149	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	
Other fee (specify)					
Other fee (specify)					

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Signature		Date	October 5, 1998	Deposit Account User ID	

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I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Signature and Deposit: October 5, 1998

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. Cook
Daria L. Jerome

Date: October 5, 1998

Serial No.: 09/037,690

Group Art Unit: 1644

Filed: 03/10/98

Examiner: F. Vandervegt

For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

File No.: 960296.94011 (now 960296.95297)

RESPONSE

Assistant Commissioner For Patents
Washington DC 20231

Dear Sir:

In response to an Office Action mailed June 4, 1998, please amend the application as follows:

In the Specification:

Page 1, lines 6-7, delete "which will issue as" and insert therefor --now --;

Page 1, line 7, delete "on" and insert therefor --, issued --.

In the Claims:

Please cancel Claims 3-5, amend Claims 1 and 8, and add new Claim 11, as follows:

1. (Amended) A method to improve the growth of an animal or the efficiency of an animal to convert feed into desired body tissue, said method comprising feeding an animal an effective amount of animal feed particles comprising an

inner core of nutrients and having an outer surface, and a layer [comprising antibodies] consisting essentially of unencapsulated antibodies on the outer surface of the inner core,

said antibodies being antibodies that can passively immunize the animal against the adverse effects of [an antigen] an ~~indigenous~~ endogenous gut peptide which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue, wherein the method achieves superior growth or feed conversion than a second method wherein a comparable amount of the antibody is fed to the animal in an unpelleted form.

5 8. (Amended) A particulate animal feed comprising an inner core of nutrients, the core having an outer surface, and a layer [of antibodies] consisting essentially of at least one unencapsulated antibody to an ~~indigenous~~ endogenous gut peptide on the outer surface of the inner core.

11. (New) A method for making an animal feed, the method comprising the steps of:

coating an antibody onto a surface of a particulate animal feed,

where in the coating step the antibody is not encapsulated in a fat.

REMARKS

In an Office Action mailed June 4, 1998 the Examiner requested that the status of the parent application be amended, rejected Claims 8 and 9 for obviousness-type double patenting, rejected Claims 1-7 under 35 U.S.C. §112, first paragraph, and rejected Claims 1-5, 7-8, and 10 under 35 U.S.C. §103(a). Each issue raised by the Examiner is considered separately below. Reconsideration of the merits of this patent application is respectfully requested.

Update to Application Status

The status of the parent application, now US Patent No. 5,725,873, is updated.

Double Patenting

The Examiner rejected Claims 8 and 9 for obviousness-type double patenting over Claim 1 of US Patent No. 5,725,873. The applicants respectfully traverse this rejection and request reconsideration. Because the patent and the pending application claim non-overlapping subject matter, the claims should be patentably distinct from one another.

Claim 1 of the '873 patent requires that the animal feed has an outer layer of an edible fat having cholecystokinin (CCK) antibodies encapsulated therein. The pending claims specifically require that the layer on the outer surface of the particles consist essentially of unencapsulated antibodies. The claims are amended to clarify this distinction which is noted in the specification. As the applicants described, an antibody to a gut peptide surprisingly retains immunological activity and is not destroyed by antibody-destroying factors, even if the antibody is simply applied to the exterior of the pellet core without encapsulation in a protective fat layer (page 3, lines 1-7). In the prior patent, issued to the same inventors, the antibody was encapsulated in fat to protect it, and the fat provided a liquid media useful to apply the antibody by spraying. An agitator was typically used to maintain a uniform mix of the encapsulated antibody in the fat. Surprisingly, the applicants have found that the protection thought to be required was not, in fact, required. As a result, the antibody can be added directly to the outer surface of a feed pellet and no agitating measures are used to stabilize the antibody. This development has important commercial benefits arising from reduced production costs, and is believed patentable over the prior patent.

Rejections Under 35 U.S.C. §112, first paragraph

The Examiner rejected Claims 1-7 for an alleged lack of enablement over the full scope of the claims. The applicants respectfully traverse the Examiner's rejection because the claims are fully enabled to one of ordinary skill in the art.

The claimed invention relates to a particulate animal feed having on its surface an unencapsulated antibody to an

indigenous gut peptide. The specific nature of the peptide is not critical to the invention. Instead, it is notable that an antibody provided on the outer surface remains active after ingestion. A person of ordinary skill in the art can readily select from any number of gut peptides which are recognized to play a role in digestion. In support of the breadth as claimed, the applicants refer the Examiner to published PCT International Application No. PCT/US95/09227 (Pub. No. WO 96/04933), of record, wherein a number of suitable gut peptides known to those skilled in the art are described for use in a related method. In addition, related US Application No. 08/807,435 (allowed), filed prior to the instant application, describes modulating feeding behavior in animals in a method that comprises the step of feeding an antibody to a gut peptide to an animal by oral administration in order to alter a physiological effect of said peptide relating to feeding or growth behavior. At least five gut peptides are identified and are shown in the application to be effective in the method. The application evidences the ability of one skilled in the art to prepare an antibody to a gut peptide without undue experimentation in selecting the gut peptide. A copy of the prior application with a set of allowed claims is enclosed for the Examiner's convenient review.

Accordingly, the applicants maintain that a person of ordinary skill in the art is given sufficient guidance in the specification to practice the invention without undue experimentation. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected Claims 1-5, 7-8 and 10 over US Patent No. 5,428,072 in view of US Patent No. 5,080,895, a paper by Albright et al., and US Patent No. 3,119,691. The applicants respectfully traverse the rejection because none of the cited documents discloses, teaches or suggests an antibody unencapsulated by fat on the surface of an animal feed and none teaches the effective use of such a feed to improve growth or feed efficiency.

In particular, the '072 patent does not disclose a feed pellet having CLA on its outer surface, nor is there any

discussion of an antibody to a gut peptide or how one would use same. The '895 patent discloses producing an antibody-containing egg yolk powder and feeding the powder to animals, but the patent describes antibodies raised only against pathogens or infectious agents. No antibodies to indigenous (self) gut peptides are raised and there is no suggestion in the '895 patent that antibodies against a self peptide would be effective after delivery by oral ingestion.

The Examiner is correct that Albright et al. teaches encapsulation of vitamin A in a lipid composition. However, Albright is not concerned with delivering antibodies, nor do the claims require encapsulation. Finally, Ludington et al. is generally inapplicable in that it does not mention using antibodies. Accordingly, none of the documents cited, alone or in combination can render obvious a particulate animal feed, or method for making or using same, as claimed. The Examiner is respectfully requested to reconsider these rejections, especially in view of the amended claims which are clarified to recite that the outer layer of the feed particle consists essentially of unencapsulated antibodies. The rejections were premised upon an alleged requirement for an encapsulated antibody in the outer layer.

Having responded to each ground of rejection, the applicants respectfully request reconsideration of the merits of this patent application.

Respectfully submitted,

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08/807,435

CCK ANTIBODIES USED TO IMPROVE FEED EFFICIENCY

Inventor(s): Mark E. Cook
Cheryl C. Miller
Julio L. Pimentel

CCK ANTIBODIES USED TO IMPROVE FEED EFFICIENCY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Patent Application Serial No. 08/286,376 filed August 5, 1994.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

N/A

FIELD OF THE INVENTION

This invention relates to eliciting biological response in mammals or poultry either by passive transfer of an antibody or upon feeding an antibody containing substance to the animal. Specifically, this invention relates to increasing food efficiency, decreasing gastrointestinal motility and decreasing satiety in animals and humans by the use of antibodies to choleocystokinin (CCK).

BACKGROUND OF THE INVENTION

The immune system, based on several kinds of specialized blood white cells, is a highly specific defense system that recognizes, eliminates and remembers foreign macromolecules and cells. While functioning properly, it can distinguish between "self" and "non-self" (foreign) materials. For example, it views tumor cells as non-self and hence attacks them, protecting animals against cancer-causing tumor cells as it protects against other invading macromolecules.

An antigen is a foreign substance that when introduced into an animal with a functioning immune system, can elicit a specific immune response such as the one mentioned above. Once activated the immune response involves, among other things, production of antibodies in the circulation system specific to that antigen. There are five distinct classes of antibodies which are also called immunoglobulins. The most abundant is IgG. The other four are IgM, IgA, IgD, and IgE. These antibodies combine with the antigen and act to neutralize or counter the effects of the antigen introduced into the animal. They accomplish this result by binding to the antigen thereby neutralizing it and preventing it from binding to other specific cell receptors.

The immune system can be used not only to fight off pathogenic antigens or harmful foreign molecules, but can be manipulated in order to elicit favorable responses which are not naturally occurring. For example, naturally occurring proteins in an animal can be neutralized via introduction of antibodies specific to that protein thereby neutralizing that protein's normal physiological affect on the animal's system.

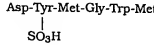
There are several ways in which an animal becomes immune responsive. For example, some antibodies are able to traverse the placenta from a mother's circulation to that of her fetus. As a result, the progeny of that mother receives natural immune protection by "inheriting" the mother's own antibodies before birth.

A second way to elicit an immune response is through introduction of an antigen into one animal, resulting in that animal developing specific antibodies to that antigen. These antibodies can then be isolated from the animal and introduced into a second animal resulting in the second animal having antibody that can bind the specific antigen.

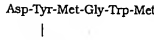
BRIEF SUMMARY OF THE INVENTION

This invention pertains to eliciting an immune response in animals and humans in order to increase food efficiency. The antibody used in this invention is an antibody specific to the peptide choleocystokinin (CCK). The choleocystokinin antibody (CCK antibody), upon introduction to the animal, causes an increased efficiency of converting food to body weight gain and through an apparent decreased gastrointestinal motility thereby increasing food efficiency.

The CCK peptide is as follows:



The CCK peptide can also be in a non-amide form:



CCK is an octapeptide that has been shown to negatively affect food intake and thus inhibit growth in both mammals (Gibbs et al, 1973) and birds (Savory and Hodgkiss, 1984). CCK antibodies have been successfully produced endogenously in pigs (Pekas and Trout, 1990; Pekas 1991) and rats (MacLaughlin et al, 1985). In both species, the adverse effects of CCK on food intake and weight gain were prevented by endogenous circulation of CCK antibodies.

The effects of CCK in domestic fowls is well known (Savory et al, 1981). CCK represents a polypeptide hormone which is released when food enters the small intestine. The presence of CCK in the gut mucosa alters gastrointestinal (GI) motility. The gizzard controls the rate in which food travels through the intestine and CCK, which is normally released after a meal is consumed, causes a decrease in gizzard contraction and an increase in intestinal contraction. This results in less time for the absorption of food and nutrients in the intestinal tract. The inventors have found that transferring CCK antibody to poultry increases feed efficiency. In other words, the birds gain more weight per pound of food.

The presence of CCK also alters the willingness to eat. CCK is responsible for what is known as the satiety effect which is a physiological effect that sharply decreases an avian's appetite. If an antibody combines with CCK, CCK is neutralized, the satiety effect is inhibited and adverse effects of endogenous CCK on gastrointestinal motility is averted. Thus, the avian gains more weight per unit of intake. It has not previously been seen that CCK antibodies function in avians or function orally and are actually able to neutralize the negative affects of CCK.

Neuropeptide Y and bombesin have similar physiological effects to CCK on mammalian systems and avian systems. These neuropeptides are also found in the gut and alter feeding behavior.

The effect of CCK antibodies on food efficiency and weight gain can be achieved by (1) passively transferring the CCK antibodies from the dam to offspring, (e.g. by injecting the breeder hen such that the offspring have increase levels of CCK antibody); (2) by feeding a yolk product high in CCK antibody directly to the animal; or (3) injecting a substance high in CCK antibody directly to the animal.

The method in which an immune response is achieved passively involves inoculating a female avian with a specific antigen which results in passively transferring the antibody to the female's offspring. This passive transfer of antibodies to CCK from the dam to the progeny resulting in improved conversion of food into body weight has not previously been seen in the art.

This invention also relates to a specific antibody containing substance produced from the egg of a hen immunized against a selected antigen wherein the substance is mixed with feed and subsequently fed to poultry to elicit altered but improved physiological response. Antibodies to CCK can be produced in laying hens, passed to the yolk, harvested from the yolk or fed as dried yolk, and used as a feed additive for improving feed efficiency in poultry has also not been previously appreciated in the art.

This invention has many advantages. One advantage is that individuals in the commercial meat industry can achieve market weight in livestock or poultry using less time and less feed thereby drastically reducing costs.

A second advantage to the present invention is that the CCK antibodies neutralize CCK but have no known harmful side affects and do not appear to affect meat quality. Also, the cost of utilizing this invention, even on a large scale, is relatively low since only .1 to 1 CCK antibody-containing egg is required per eight pounds of feed.

In addition, using the method of feeding the antibody to domesticated animals is relatively low in labor costs since the antibody can simply be mixed with feed and thus, not every individual animal must be injected with the antibody. Also, there is no need to separate or isolate the antibody from the egg since whole egg or yolk can simply be spray dried and fed directly.

Another advantage of this invention is that it counteracts the negative affect of feeding raw soybean meal to poultry or livestock. For example, a typical chick diet contains 40% soybean meal. However, raw soybean meal cannot be fed to poultry because it contains trypsin inhibitor which inhibits the ability of trypsin to digest protein. Therefore, raw soybean meal causes increased levels of CCK with a concurrent decrease in feed efficiency. In order to counter this effect, soybeans must be heat treated in order to be fed to poultry. The typical process for preparing soybean involves heating the beans, extracting the oils and using the remaining meal for chick feed. Specifically,

the beans must be heated to at least 121°C for approximately 20-40 minutes. There are several problems associated with preparing soybeans for poultry feed. One is that the heating process must be performed at an extremely high temperature to ensure destruction of the trypsin inhibition factor. Secondly, heating has a negative impact on the quality of proteins in the soy meal and makes the denatured protein difficult to digest properly. However, the inventors have found that CCK antibodies protect against the negative effects of feeding raw soybeans to fowl.

In addition to soybean, there are a number of other plants that contain trypsin inhibitor, including wheat, barley, lima beans and various legumes. It is predicted that the CCK antibody will also protect against the negative affects of feeding products made from wheat, barley, lima bean or legumes to poultry or livestock.

This invention also has many advantages over what is currently being used in the poultry and livestock industries. Antibiotics are currently used in the commercial animal industry in order to increase food efficiency and weight gain. However, antibiotics leave a drug residue in the animal's tissue. Therefore, the animal must go through "withdrawal time". Withdrawal time is an amount of time sufficient for the antibiotic to clear animal tissues. During withdrawal time, the animal cannot be slaughtered for human consumption. Additionally, any eggs or milk produced cannot be utilized for human use. This precaution is utilized because of the concern that human consumption of milk with traces of penicillin, for example, will cause increase resistance to antibiotics in man, eventually rendering the use of antibiotics to fight bacterial diseases useless.

Secondly, the use of antibiotics over a long period of time can potentially cause an increased number of microorganisms able to infect an animal because these organisms slowly gain resistance due to constant exposure to the antibiotic. Thus, future bacterial diseases will be difficult if not impossible to treat.

CCK also has the same effects of increased GI motility and satiety inhibition in mammals (Pekas and Trout, 1990). It is a well known fact that mammalian species passively transfer antibodies to their progeny as do avians and that mammals respond to CCK autoimmunization as do avians. The dam's antibodies are also identical to those passively transferred to the progeny in avians as well as mammals. Similarly, feeding raw soybean exerts analogous

increases in CCK production in mammals as it does in birds (Weller et al, 1990; Chohen et al, 1993; Can J An Sci 73; 401). Therefore, based on the aforementioned facts, the protective effects of actively fed and passively transferred CCK antibodies against satiety and poor feed conversion resulting from CCK observed in avians would also be seen in mammals. Using CCK on various livestock such as cattle and swine would drastically increase their final weight using the same amount of animal meal. Thus the costs to produce an animal of market size is decreased and this would have an enormously beneficial effect on the livestock industry.

The invention would be highly beneficial to humans who are underweight or have problems maintaining their weight. Additionally, individuals with eating disorders would benefit from this invention because their food intake could be controlled.

As previously stated, there are other gastrointestinal peptides or hormones which have an effect on an animal's feeding behavior and digestion. The example of CCK and the method of using CCK antibodies directed toward that peptide in order to prevent CCK's adverse effects suggests that similar responses could be achieved using other antibodies specific to gastrointestinal peptides or hormones. For example, gastrin is involved in signaling acid secretion into the gut and has a trophic action on gastric mucosa leading to hyperplasia. An antibody to gastrin could be used to decrease acid secretion in animals with gastric ulcers or in cases where there is gastric ELC cell carcinoid tumors due to prolonged hypergastrinemia. Gut somatostatin inhibits food intake in fed animals as well as many other gut activities. An antibody to somatostatin could prevent its inhibitory activities. Bombesin stimulates a release of CCK. One could hypothesize that inhibiting bombesin using an antibody specific to bombesin may result in responses similar to antibodies specific to CCK. Neuropeptide Y has been reported to be a stimulus in feeding. It may be possible to inhibit its activity and regulate obesity in animals prone to develop such problems. The biological activity of other peptides which regulate intestinal motility and other functional properties of the intestine could be regulated using the technology described.

In general, by generating antibodies to peptides, hormones, cytokines, etc. that regulate biochemical, metabolic, physiological, and/or behavioral processes, it may be possible to regulate or alter an animal's system to compensate for a physical abnormality or accentuate a normal function.

DETAILED DESCRIPTION OF THE INVENTION

As previously mentioned, there are three modes in eliciting an immune response to CCK in mammals or poultry: passive transfer, active feeding, and active inoculation.

The mode of this invention which relates to passively transferring antibodies involves injecting laying hens with CCK wherein the hens produce antibodies specific to CCK and, as a result, those antibodies are then passively transferred into the egg yolk of eggs laid by the hens. The chick embryo absorbs the CCK antibody during embryonic development. Thereafter, the CCK antibodies become circulating in the hatched chick's bloodstream as well as passed to the gastrointestinal tract.

Either purified CCK or synthesized CCK peptide can be used. Well known means in the art can be used for purifying the CCK peptide such as fractionization, chromatography, precipitation or extraction. However, CCK should be conjugated with a carrier or foreign protein for use as the antigen. CCK alone has a molecular weight less than 1,500 Daltons. In order to invoke an immune response, a molecular weight of at least 10,000 Daltons is required. Therefore, the CCK peptide should be conjugated with a carrier protein with a molecular weight of approximately 8,000 Daltons or more in order for the conjugate to elicit an immune response. Carriers include a wide variety of conventionally known substances but commonly entail bovine gamma globulin or keyhole limpet hemocyanin.

The CCK peptide conjugated to its carrier protein is injected into the target animal with a common adjuvant. The CCK-carrier conjugate can be emulsified in Freund's complete adjuvant, for example. If mammals are the target animals, then subsequent inoculations should consist of incomplete adjuvant.

Another mode of this invention involves orally feeding a CCK antibody containing substance produced from eggs of a CCK vaccinated hen. The CCK antibody containing eggs are prepared and mixed into animal meal. Poultry or mammals which consume this antibody containing meal soon show beneficial response by preventing the satiety effects specific to CCK.

The production of CCK antibody for oral administration can be done by utilizing known technology for producing antibodies in egg yolks. In that process, hens are challenged by injecting them with CCK conjugated to a carrier protein. In response to exposure to the CCK antigen, the eggs laid by

these hens contain high levels of CCK antibody in the yolk. Automated systems then separate and spray dry the yolks into a powder. The yolks can alternatively be lyophilized. This standard technique is well established in the art for producing various antibodies for other purposes (e.g. diagnoses, resistance to pathogens, etc.)

Whole eggs may be used and it is therefore not necessary to separate the yolk from the albumen. Typically, .1 to 1 CCK containing egg is used per 8 pounds of feed.

Chickens are the most preferable source of eggs but eggs from turkeys, geese, ducks and the like may also be used.

While eggs are the logical source of massive quantities of antibodies, it is possible to collect the antibodies from whole blood, plasma or serum when chickens are processed for meat. In addition, whole blood, plasma or serum from inoculated livestock may be another source of antibodies as well as milk derived from an inoculated cow or goat. Additionally, another source of antibody production is through cell fusion using hybridoma techniques, genetically altered cell cultures or fermentation using recombinant technology.

A third mode of this invention is via inoculation. CCK antibodies can be directly injected into a target animal in order to elicit the desired response of satiety and improved feed conversion.

The target animal receiving the CCK antibody varies greatly. Commercial animals such as livestock, poultry and pelt-animals (e.g. mink, sable, etc.) are ideal candidates. Additionally, humans who have difficulty gaining weight are also considered within the scope of this invention.

PASSIVELY TRANSFERRED CCK ANTIBODIES ON PERFORMANCE OF YOUNG LEGHORN CHICKS.

Example 1

Methods

Choleocystokinin (CCK-8) (Fragment 26-33 amide with sulfated tyrosine) was conjugated to keyhole limpet hemocyanin (KLH) using glutaraldehyde and was emulsified with Freund's complete adjuvant (1:1) and injected (100ug CCK) into 11 Single Comb White Leghorn laying hens. A second injection of the CCK-8 conjugate in Freund's incomplete adjuvant was injected 7 days after primary injection. Another group of control hens which did not receive the CCK injection were also used. Hens (control and CCK injected) were fertilized (artificially using semen collected from New Hampshire

roosters). Fertile eggs collected 5 months after the initial injection were used to determine chick performance as a result of passively transferred CCK antibodies. Fifteen chicks hatched from the control hens and 15 chicks hatched from the CCK injected hens were raised in battery brooders on corn-soybean meal based diets for 6 weeks. Body weight gain and feed consumption data were collected.

Results

Chicks from CCK injected hens had improved feed conversion (less feed per pound of gain) which was 14% better than chicks from the control hens. Also, feed intake was increased in CCK birds. The results are shown as Table I.

TABLE I

Antibody Treatment	6 Week Gain*	% Change	6 Week Intake*	% Change	6 Week Conversion	% Change
Control	297		745		2.51	
CCK	352	+18	756	+1	2.15	-14

*Body weight, body wt gain and feed intake are measured in grams.

Example 2

Methods

Eggs from hens immunized with CCK (as shown in Example 1) and from control hens were collected at approximately 10 months after the primary inoculation. Two pens of 13 chicks (representing both the control and CCK immunized hens) were fed a corn-soybean meal based diet to determine if passively transferred CCK antibodies would influence performance as seen in Example 1. Birds were raised for 4 weeks. Body weights and feed consumption were determined.

Results

Feed conversion was improved 2% in chicks from CCK immunized hens when compared to chicks from control hens. The results are shown as Table II.

TABLE II

Treatment	4 Week Weight*	% Change	4 Week Intake*	% Change	4 Week Conversion	% Change
Control	158		383		2.42	
CCK	151	-4	360	-6	2.38	-2

*Body weight, body wt gain and feed intake are measured in grams.

Example 3

Methods

Fertile eggs were collected approximately 8 months after primary inoculation from control and CCK injected hens (immunization as described in Example 1) and used to study the effects of CCK immunization on progeny performance. Two pens of 17 progeny chicks per pen from CCK injected hens and 2 pens of 17 progeny chicks per pen from control hens were raised for 4 weeks. Body weight and feed consumption were measured.

Results

Chicks from CCK injected hens had a 5.2% improvement in feed conversion than chicks from control hens. The results are shown as Table III.

TABLE III

Treatment	4 Week Weight*	% Change	4 Week Intake*	% Change	4 Week Conversion	% Change
Control	246		473		1.92	
CCK	245	0	447	-5.5	1.82	-5.2

*Body weight, body wt gain and feed intake are measured in grams.

Example 4

Methods

In this study, 2 pens of 15 chicks per pen from CCK immunized hens (as shown in Example 1 and 7 months following the hen's primary inoculation) and 2 pens of 12 chicks per pen from control hens were raised on a corn-soybean meal based diet supplemented with 5% raw soybeans for 3 weeks (raw soybeans were used to stimulate CCK production). Body weight and feed consumption were measured.

Results

Chicks from CCK injected hens had a 10% improvement in feed conversion when compared to chicks from control hens. The results are shown in Table IV.

TABLE IV

Treatment	3 Week Weight*	% Change	3 Week Intake*	% Change	3 Week Conversion	% Change
Control	169		395		2.34	
CCK	161	-5	338	-14	2.10	-10

*Body weight, body wt gain and feed intake are measured in grams.

PROTOCOL FOR THE EFFECTS OF PASSIVELY TRANSFERRED CCK ANTIBODY ON THE PERFORMANCE OF YOUNG BROILER CHICKS.

Example 5

Methods

Broiler breeders were immunized with CCK conjugated to KLH using the protocol described in example 1. Since these breeders were maintained on the floor, fertile eggs were produced as a result of natural matings. A total of 10 hens received the CCK immunization (antigen prepared as in example 1 for Leghorns), and 10 hens served as controls. Approximately 21 to 30 days after the primary inoculation, fertile eggs were collected from the control and CCK immunized hens. Seven broiler chicks from the control hens and 7 broiler chicks from the CCK injected hens were hatched and raised in a battery brooder for 3 weeks. Body weight and feed consumption were measured.

Results

Feed conversion was improved 20% and body weight 8% in broiler chicks from CCK immunized hens as compared to broiler chicks from control hens. See Table V for results.

TABLE V

Treatment	3 Week Weight*	% Change	3 Week Intake*	% Change	3 Week Conversion	% Change
Control	396		604		1.53	
CCK	427	+8	526	-13	1.23	-20

*Body weight, body wt gain and feed intake are measured in grams.

Example 6

Methods

Two pens of 6 chicks from CCK immunized broiler breeders 7 weeks after the primary inoculation as in Example 5 and 2 pens of 6 chicks per pen from the control hens were hatched and raised to 3 weeks of age on a standard broiler type diet. Body weight and feed consumption were measured.

Results

Broiler chicks from CCK immunized hens gained 16% more body weight and converted food 12.5% more efficiently than chicks from the control hens. See Table VI for results.

TABLE VI

Treatment	3 Week Weight*	% Change	3 Week Intake*	% Change	3 Week Conversion	% Change
Control	380		547		1.44	
CCK	441	+16	547	0	1.26	-12.5

*Body weight, body wt gain and feed intake are measured in grams.

FEEDING EGG YOLKS FROM CONTROL AND CCK IMMUNIZED HENS.

Example 7

Methods

Control or CCK immunized hens were prepared as described in Example 1. Eggs from control and CCK immunized hens were collected after at least 21 days following the primary inoculation. Yolks were collected from the eggs (albumen was discarded) and control or anti-CCK yolks were separately pooled, frozen, then freeze dried. The control and CCK antibody dried yolks were then ground and added to a standard corn-soybean based diet at .5, 1.0, or 5% of the diet (weight by weight) creating 3 control treatments and 3 anti-CCK treatments. Each dietary treatment was fed to two pens of 9 leghorn type chicks for 4 weeks. Body weight gains, feed consumption, and feed conversion were determined.

Results

As the level of anti-CCK egg yolk increased, body weight gain increased relative to those fed the control egg yolk. At each level of anti-CCK egg yolk feeding, feed conversion was improved over those fed the control yolk. See Table VII for results.

TABLE VII

Treatment	% Fed	----------0-4 weeks of age---------- Feed Intake*	Feed Conversion
Control Yolk	.5	692	2.88
CCK Yolk	.5	680	2.50
Control Yolk	1.0	656	2.39
CCK Yolk	1.0	649	2.29
Control Yolk	5	712	2.55
CCK Yolk	5	772	2.49

*Body weight, body wt gain and feed intake are measured in grams.

EFFECTS OF PASSIVELY TRANSFERRING CCK ANTIBODY IN PREVENTING THE NEGATIVE EFFECTS OF FEEDING RAW SOYBEANS ON FEED CONVERSION.

Example 8

Methods

Immunized hens (Leghorns) were prepared as described in Example 1. Hens were artificially fertilized and eggs were collected and incubated. Chicks (Single Comb White Leghorn X New Hampshire) were hatched and 2 pens of 12 chicks were assigned to each of 4 treatments. The treatments included 2 sources of chicks (progeny from control or CCK immunized hens) factorially arranged with 2 dietary treatments (5 or 10% raw soybeans at the expense of diet). The chicks were fed the diets for 4 weeks and body weight and feed consumption were measured.

Results

Chicks from CCK immunized hens had improved feed conversion (11% to 19%) when compared to their respective control diets. As the level of raw soybeans increased in the diet, feed conversion was poorer (12% poorer in the control progeny, but only 6% poorer in the progeny chicks from the CCK injected hens). See Table VIII for results.

TABLE VIII

% Raw Soybean	Passive CCK Antibody	4 Week Weight*	% Change	4 Week Conversion	% Change
5	-	202		2.63	
5	+	205	+1.5	2.34	-11
10	-	192		2.94	
10	+	197	+2.6	2.48	-19

*Body weight, body wt gain and feed intake are measured in grams.

FEEDING ANTI-PEPTIDES TO BROILER CHICKS

Example 9

Summary: Broiler chicks were purchased from an outside vendor and fed various antibodies to peptides of GI tract to establish any type of phenomena that may occur related to body weight and/or feed conversion.

Animals:

Species:	Broiler Chicken
Strain:	Avian X Avian
Source:	Northern Hatcheries (Beaver Dam, WI)
Vaccinations:	Mareks, Gumboro, New Castle/Bronchitis, AE
Sex:	Male
Number of each	32

Feeding Protocol (Treatments)

Diets: **(g/kg)**

	Peptide Identification	Lot Number	0.5
bGG Control	N3 Control	E-457A	X
Bombesin	P6	P6-32995	X
Motilin	P7	P7-32995	X
Neuropeptide Y	P8	P8-32995	X

Trial Set-Up:

Number of Pens	Birds per Pen	Floor	Battery
8	4		X
Pens per Treatment	Birds per Treatment		
2	8		

Results:

Treatment	3 Week Body Wt (g)	0-3 Body Wt Gain (g)	0-3 Feed/Bird	0-3 Feed/Gain
Control	543	503	786	1.56
Bombesin	530	490	774	1.58
Motilin	554	494	795	1.61
Neuropeptide Y	537	495	711	1.44

The above data show that chicks fed bombesin, motilin and neuropeptide Y all show weight gain comparable to control. In particular, the use of neuropeptide Y results in substantially the same weight gain over time as control, but with significantly less feed than control.

FEEDING AVENO AND NEUROPEPTIDE Y TO BROILER CHICKS

Example 10

Summary: Broiler chicks were hatched from UW stock and fed yolk from hens injected with Aveno or Neuropeptide Y when compared to control powder from N3 series.

Animals:

Species:	Broiler Chicken
Strain:	Petersen X Arbor Acre
Source:	UW Stock
Vaccinations:	None
Sex:	Mixed
Number of each	175

Feeding Protocol (Treatments)

Diets: **(g of egg yolk antibody powder per kg feed)**

	Peptide Identification	Lot Number	0.25	0.5	1.0
bGG Control	N3 Control	E457A		X	
Reverse Bravo	P10	P10-61695		X	X
Aveno	P11	P11-61695		X	X
Neuropeptide Y	P8	P8-32995	X	X	

Trial Set-up:

Number of Pens	Birds per Pen	Floor	Battery
35	5		X
Pens per Treatment	Birds per Treatment		
5	25		

Results: Feed Conversions

Treatment	1-3 Feed/Gain
Control (0.5)	1.63
Aveno (0.5)	
Aveno (1.0)	
Reverse (0.5)	
Reverse (1.0)	
Peptide 8 (0.25)	1.58
Peptide 8 (0.5)	1.71

Note: This trial started when the birds were one week of age, therefore we will not have a 0-2 feed/gain.

Treatment (g yolk/kg feed)	3 Wk Weight (gain) (g)
Control	418 (328)
Aveno (0.5)	
Aveno (1.5)	
Reverse (0.5)	
Reverse (1.0)	
Peptide 8 (0.25)	475 (379)
Peptide 8 (0.5)	442 (349)

These data show that feeding neuropeptide Y (Peptide 8) resulted in chicks having significantly greater weight gain versus control chicks.

FEEDING ANTI-BRAVO ANTIBODIES TO BROILER CHICKS

Example 11

Summary: Broiler chicks were hatched at the UW poultry research lab and fed Anti-Bravo from a specified lot of Gutteridge product (G111S) to monitor a dose response similar to these seen with the N-series products. Also monitor Peptide 8 to see if it has similar properties to Bravo.

Animals:

Species:	Broiler Chicken
Strain:	Petersen X Arbor Acre
Source:	UW stock
Vaccinations:	none
Sex:	Mixed
Number of each	75

Fertility Information:

Treatment	Infertile	Early Deads	No Hatch	Hatched
Control	66	24	35	415
Bravo				

Feeding Protocol (Treatments)

Diets: **(g/kg)**

	Lot Number	0.25
N3 Control	E-457A	X
Bravo (G111S)	A2-61695	X
Peptide 8 (Neuro Y)	32995	X

Trial Set-up: (Birds per Rx=25)

Number of Pens	Birds per Pen	Floor	Battery	Passive	Control (bGG)
15	5		X		75

Feed:

Rx	Control 0.25	G111S 0.25	Peptide 8 0.25
1	X		
2		X	
3			X

Results: Feed Conversion

RX	0-1 Feed/Gain	0-2 Feed/Gain	0-3 Feed/Gain
Control	1.66	1.60	1.96
G. Bravo (0.25)	1.67 (-1)	1.62 (-2)	1.89 (7)
Peptide 8	1.63	1.61	1.83 (13)

Body Weights (gains):

Rx	1 wk (gain)(g)	2 wk (gain)(g)	3 wk (gain)(g)
Control	111 (70)	247 (205)	432 (390)
G. Bravo (0.25)	102 (61)	231 (190)	407 (366)
Peptide 8	110 (69)	262 (221)	465 (423)

Note: These suppressions in weight gain for Bravo are probably due to the high titer of the product used.

These data show that feeding neuropeptide Y (Peptide 8) resulted in chicks having significantly greater weight gain versus control.

FEEDING PEPTIDES 6, 7 & 8 TO BROILER CHICKS

Example 12

Summary: To determine if there is an effect in improving feed conversion when feeding any of these peptides to broiler chicks.

Animals:

Species:	Broiler Chicken
Strain:	Petersen X Arbor Acre
Source:	UW Stock (Controls Only)
Vaccinations:	NONE
Sex:	Mixed
Number of each	100

Feeding Protocol (Treatments)

Diets: **(g/kg)**

Treatments	Lot Number	0.25
Control	E457A	X
Peptide 6 (Bombesin)	P32995	X
Peptide 7 (Motilin)	P32995	X
Peptide 8 (Neuropeptide Y)	P32995	X

Trial Set-up:

Number of Pens	Birds per Pen	Floor	Battery
20	5		X
Pens per Treatment	Birds per Treatment		
5	25		

Results:

Treatment	0-1 Feed/Gain	0-2 Feed/Gain	0-3 Feed/Gain
Control	1.51	1.68	1.71
Peptide 6	1.48	1.58	1.64
Peptide 7	1.63	1.59	1.63
Peptide 8	1.38	1.55	1.69

Body Weights (grams):

Treatment	1 Week	2 Week	3 Week
Control	119 (72)	258 (211)	480 (433)
Peptide 6	115 (70)	274 (229)	509 (463)
Peptide 7	116 (71)	272 (226)	505 (460)
Peptide 8	124 (78)	296 (250)	562 (516)

Note: Chicks were hatched from BgG hens instead of purchased.

These data show that bombesin (Peptide 6), motilin (Peptide 7) and neuropeptide Y (Peptide 8) all significantly increased body weights of chicks versus control. In each case, the peptide resulted in chicks with greater body weight for the same amount of feed fed to the chicks.

FEEDING PEPTIDES 6, 7 AND 8 TO RATS

Example 13

Summary: Rats purchased from Harlan Sprague Dawley were fed antibodies to GI tract peptides from a specified lot to establish the appropriate dose level to increase or decrease consumption after 72 hours.

Animals:

Species:	Rat
Strain:	Sprague Dawley
Source:	Harlan Sprague Dawley Madison, WI
Vaccinations:	none
Sex:	Male
Number of each	41

Feeding Protocol (Treatments)

Diets: **(g/kg)**

	Lot Number	0.25	0.50
bGG Control	E457A	X	
Peptide 6	32995	X	X
Peptide 7	32995	X	X
Peptide 8	32995	X	X

Trial Set-up:

Number of Pens	Rat per Cage	Floor	Cage
41	1		X
Cages per Treatment	6		

Results:

Treatment (g yolk/kg feed)	0-3 Day Consumption (g)	0-3 Feed/Kg of Body Wt
Control	76.16	205.343
Peptide 6 (0.25)	71.2	187.86
Peptide 7 (0.25)	71.2	182.85
Peptide 8 (0.25)	71	186.63
Peptide 6 (0.5)	72.5	193.67
Peptide 7 (0.5)	70.8	189.25
Peptide 8 (0.5)	72	189.86

FEEDING BRAVO TO PIGS

Example 14

Summary: Pigs were fed Bravo to establish bioactivity relating to feeding and growth behavior.

Results:

	(lbs)	(kg)	(kg)	(kg)		
Treatment*	2 week wt	0-2 gain	adg	0-2 Feed consumption	0-2 feed/kg body wt.	0-2 feed/gain
Control	66.3	10.4	0.741	19.31	0.638	1.870
0.25	63.8	9.8	0.703	19.19	0.663	1.959
0.75	64.7	10.7	0.763	19.43	0.661	1.821
2.5	68.3	11.1	0.790	20.66	0.660	1.878

* grams of egg yolk antibody powder/kg feed

We claim:

1. A method of modulating feeding behavior in animals, comprising the step of feeding an antibody to a gut peptide to an animal in order to alter a physiological effect of said peptide relating to feeding or growth behavior.

2. The method of claim 1 wherein said gut peptide is choleocystokinin.

3. The method of claim 2 wherein said choleocystokinin is purified choleocystokinin peptide.

4. The method of claim 2 wherein said choleocystokinin is synthetic choleocystokinin peptide.

5. The method of claim 2 wherein said choleocystokinin is sulfated.

6. The method of claim 2 wherein said choleocystokinin is an amide.

7. The method of claim 2 wherein said feeding improves feed efficiency.

8. The method of claim 7 wherein said feeding improves growth rate.

9. The method of claim 1 wherein said gut peptide is bombesin.

10. The method of claim 1 wherein said gut peptide is neuropeptide Y.

11. The method of claim 1 wherein said gut peptide is gastrin.

12. The method of claim 1 wherein said gut peptide is somatostatin.

13. The method of claim 1 wherein said animal is an avian.

14. The method of claim 13 wherein said avian is a chicken.

15. The method of claim 1 wherein said animal is a mammal.

16. The method of claim 15 wherein said mammal is selected from the group consisting of a porcine, a bovid, an ovine, a caprine, a rodentia and a homo sapien.

17. A method of modulating feeding behavior in animals, comprising the steps of:

immunizing a producer animal with a gut peptide so that said producer animal produces an antibody to said gut peptide;

isolating a substance containing said gut peptide antibody from said producer animal; and

feeding said gut peptide antibody to an animal in order to alter growth, food efficiency, food intake or intestinal motility.

18. The method of claim 17 wherein said gut peptide is choleocystokinin.

19. The method of claim 17 wherein said gut peptide is bombesin.

20. The method of claim 17 wherein said gut peptide is neuropeptide Y.

21. The method of claim 17 wherein said gut peptide is gastrin.

22. The method of claim 17 wherein said gut peptide is somatostatin.

23. The method of claim 17 wherein said choleocystokinin is conjugated to a carrier protein.

24. The method of claim 23 wherein said carrier protein is keyhole limpet hemocyanin.

25. The method of claim 23 wherein said carrier protein is bovine gamma globulin.

26. The method of claim 23 wherein said choleocystokinin conjugated to said carrier protein has a molecular weight of at least 8,000 Daltons.

27. The method of claim 17 wherein said substance containing said gut peptide antibody is selected from the group consisting of milk, whole egg and egg yolk.

28. The method of claim 17 wherein said substance containing said gut peptide antibody is selected from the group consisting of whole blood, blood serum and blood plasma, and further including the step of separating the gut peptide antibody from said substance prior to feeding said gut peptide antibody to said animal.

CCK ANTIBODIES USED TO IMPROVE FEED EFFICIENCY

ABSTRACT OF THE DISCLOSURE

A method of increasing food efficiency in both avians and mammals by using antibodies to gut peptides such as choleocystokinin to elicit a biological response which decreases gastrointestinal motility, reduces satiety or improves feed efficiency.

ALLOWED CLAIMS
for
P97060US – C,M,P

---

1. A method of modulating feeding behavior in animals, comprising the step of feeding an antibody to a gut peptide to an animal by oral administration in order to alter a physiological effect of said peptide relating to feeding or growth behavior.

2. The method of claim 1 wherein said gut peptide is choleocystokinin.

3. The method of claim 2 wherein said choleocystokinin is purified choleocystokinin peptide.

4. The method of claim 2 wherein said choleocystokinin is synthetic choleocystokinin peptide.

5. The method of claim 2 wherein said choleocystokinin is sulfated.

6. The method of claim 2 wherein said choleocystokinin is an amide.

9. The method of claim 1 wherein said gut peptide is bombesin.

10. The method of claim 1 wherein said gut peptide is neuropeptide Y.

11. The method of claim 1 wherein said gut peptide is gastrin.

12. The method of claim 1 wherein said gut peptide is somatostatin.

13. The method of claim 1 wherein said animal is an avian.

14. The method of claim 13 wherein said avian is a chicken.

15. The method of claim 1 wherein said animal is a mammal.

16. The method of claim 15 wherein said mammal is selected from the group consisting of a porcine, a bovid, an ovine, a caprine, a rodentia and a homo sapien.

17. A method of modulating feeding behavior in animals, comprising the steps of:

immunizing a producer animal with a gut peptide so that said producer animal produces an antibody to said gut peptide;

isolating a substance containing said gut peptide antibody from said producer animal; and

feeding said substance containing said gut peptide antibody to an animal by oral administration.

18. The method of claim 17 wherein said gut peptide is choleocystokinin.

19. The method of claim 17 wherein said gut peptide is bombesin.

20. The method of claim 17 wherein said gut peptide is neuropeptide Y.

21. The method of claim 17 wherein said gut peptide is gastrin.

22. The method of claim 17 wherein said gut peptide is somatostatin.

23. The method of claim 18 wherein said choleocystokinin is conjugated to a carrier protein.

24. The method of claim 23 wherein said carrier protein is keyhole limpet hemocyanin.

25. The method of claim 23 wherein said carrier protein is bovine gamma globulin.

27. The method of claim 17 wherein said substance containing said gut peptide antibody is selected from the group consisting of milk, whole egg and egg yolk.

28. The method of claim 17 wherein said substance containing said gut peptide antibody is selected from the group consisting of whole blood, blood serum and blood plasma.

29. The method of claim 17 further including the steps of separating the gut peptide antibody from said substance, and thereafter feeding said gut peptide antibody to said animal.

30. The method of claim 17 wherein said animal is selected from the group consisting of an avian, a porcine, a bovine, an ovine, a caprine, a rodentia and a homo sapien.

Receipt

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Signature and Deposit: October 21, 1998

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. Cook
Daria L. Jerome

Date: October 21, 1998

Serial No.: 09/037,690

Group Art Unit: 1644

Filed: 03/10/98

Examiner: F. VanderVegt

For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

File No.: 960296.94011 (now 960296.95297)

REQUEST FOR CORRECTED FILING RECEIPT

Assistant Commissioner For Patents
Application Processing Division
Customers Correction Branch
Washington DC 20231

Dear Sir:

An error was noted in the Corrected Filing Receipt received in connection with the above-noted patent application.

In the title, the word "Improving" is still misspelled.

Also, the applicants respectfully request that the Office update the attorney docket number so that the last five digits are 95297, if possible.

Thank you for your attention to this request.

Respectfully submitted,

Bennett J. Berson
Reg. No. 37,094
Attorney for Applicants
QUARLES & BRADY
P.O. Box 2113
Madison, WI 53701-2113
(608) 251-5000

QBMAD\173048

PTO-103X
(Rev. 7-93)

FILING RECEIPT

CORRECTED

OCT 26 1998

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	PRELIMINARY	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/037,690	03/10/98	1644	$1,002.00	960296.~~94011~~ 95297	0	10	4

BENNETT J.BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

Receipt is acknowledged of this patent application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Addressed Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s) MARK E. COOK, MADISON, WI; DARIA L. JEROME, FRAZEE, MN.

CONTINUING DATA AS CLAIMED BY APPLICANT-
THIS APPLN IS A CIP OF 08/684,785 07/22/96 PAT 5,725,873

FOREIGN FILING LICENSE GRANTED 03/27/98
TITLE
METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

PRELIMINARY CLASS: 424

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98 OCT 30 PM 2:23

(see reverse)

EXPRESS MAIL LABEL NO. _____

PTO/SB/17 (1/98)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL

Patent fees are subject to annual revision on October 1. These are the fees effective October 1, 1997.
Small Entity payments must be supported by a small entity statement otherwise large entity fees must be paid. See Forms PTO/SB/09-12

TOTAL AMOUNT OF $

Complete if Known	
Application Number	09/037,690
Filing Date	3/10/98
First Named Inventor	Mark E. Cook
Group Art Unit	1644
Examiner Name	F. Pierre VanderVegt
Attorney Docket	960296.95297

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17 [ ] Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. [ ] Payment Enclosed: [ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fees effective 10/01/97)

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility filing fee	
106	330	206	165	Design filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)

2. CLAIMS

	Extra		Fee from below	Fee Paid
Total Claims	-20**=	X	=	
Independent Claims	-3**=	X	=	
Multiple Dependent Claims			=	

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	22	203	11	Claims in excess of 20
102	82	202	41	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim
109	80	209	40	**Reissue independent claims over original patent
110	22	210	11	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)		Fee
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	*920	112	*920	Requesting publication of SIR prior to Examiner action	
113	*1,840	113	*1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	890	217	445	Extension for reply within third month	
118	1,510	218	755	Extension for reply within fourth month	
128	2,060	228	1,030	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,320	241	660	Petition to revive unintentionally abandoned application	
142	1,320	242	660	Utility issue fee (or reissue)	
143	450	243	225	Design issue fee	
144	670	244	335	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	Filing a submission after final rejection (37 CFR 1.129(a))	
149	790	249	395	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify): _____

Other fee (specify): _____

SUBTOTAL (3) ($)

* Reduced by Basic Filing Fee Paid

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	Bennett J. Bereon			Reg. Number	37,094
Signature		Date	October 21, 1998	Deposit Account User ID	

GBMAD\173049

Interview Summary

Application No.	Applicant(s)
08/037,690	Cook et al
Examiner: F. Pierre VanderVegt	Group Art Unit: 1844

All participants (applicant, applicant's representative, PTO personnel):

(1) *F. Pierre VanderVegt* (3) _____

(2) *Bennett Berson* (4) _____

Date of Interview *Dec 4, 1998*

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description:

Agreement ☒ was reached. ☐ was not reached.

Claim(s) discussed: *1, 7, 8, and 10-13*

Identification of prior art discussed:
None in particular.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Applicant agreed to the Examiner's amendment for the purpose of clearly define the claimed invention in terms which are consistent with the instent specification.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendents which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a seperate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☒ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a seperate record of the interview unless box 1 above is also checked.

F. P. VanderVegt

Examiner Note: You must sign and stamp this form unless it is an attachment to a signed Office action.

Notice of Allowability

Application No.	Applicant(s)
09/037,690	Cook et al
Examiner: F. Pierre VanderVegt	Group Art Unit: 1644

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to *paper filed 10/9/98*.

☒ The allowed claim(s) is/are *1, 2, 6, 8, 9, 12, and 13*.

☐ The drawings filed on _____ are accepteble.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents heve been

☐ received.

☐ received in Application No. (Series Code/Seriel Number) _____.

☐ received in this netional staga application from the Internetionel Bureeu (PCT Rule 17.2(e)).

*Certified copies not received: _____.

☐ Acknowledgement is made of e claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this epplicetion. Extensions of time may be obtained under the provisions of 37 CFR 1.136(e).

☐ Note the ettached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses thet the oath or decleration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☐ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicent to be informal.

☐ including changes required by the Notice of Draftsperson's Patent Drewing Review, PTO-948, attached hereto or to Paper No. _____.

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the applicetion number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separete pepar with a transmittal lettter addressed to the Officiel Draftsperson.

☐ Note the attached Exeminer's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicent hes received e Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER end DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Peper No(s). 5

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Petent Application, PTO-152

☒ Interview Summery, PTO-413

☒ Examiner's Amendment/Comment

☐ Exeminer's Comment Regerding Requirement for Deposit of Biologicel Material

☒ Examiner's Stetement of Reasons for Allowance

DETAILED ACTION

This application is a continuation of application S.N. 08/684,785.

Claims 3-5 have been canceled and new claim 11 has been added. Claims 1 and 6-11 are currently pending in this application.

EXAMINER'S AMENDMENT

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Bennett Berson on November 24, 1998.

2. The application has been amended as follows:

IN THE CLAIMS:

Claim 11 has been canceled without prejudice.

In claim 1, line 11, the recitation "indigenous" has been replaced by --endogenous--.

In claim 8, line 4, the recitation "indigenous" has been replaced by --endogenous--.

Claims 7 and 10 have been canceled and replaced by the following new claims:

12. A method to improve the growth of an animal or the efficiency of an animal to convert feed into desired body tissue, said method comprising feeding an animal an effective amount of animal feed particles comprising an inner core of nutrients and having an outer surface, and a layer consisting essentially of unencapsulated antibodies and conjugated linoleic acid on the outer surface of the inner core,

B1

16

said antibodies being antibodies that can passively immunize the animal against the adverse effects of an endogenous gut peptide which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue, wherein the method achieves superior growth or feed conversion than a second method wherein the antibody is fed to the animal in an unpelleted form.

13. A particulate animal feed comprising an inner core of nutrients, the core having an outer surface, and a layer consisting essentially of conjugated linoleic acid and at least one unencapsulated antibody to an endogenous gut peptide on the outer surface of the inner core.

3. Claims 1 and 6-11 do not have the benefit under 35 USC § 120 of the filing date of application S.N. 08/684,785. For example, "consisting essentially of unencapsulated antibodies on the outer surface" (claim 1), "consisting essentially of at least one unencapsulated antibody to an endogenous gut peptide" (claim 8) and "where in the coating step the antibody is not encapsulated in a fat" (claim 11) were not disclosed in the priority application. The priority application discloses only the encapsulating the antibodies of the coating in a fat. Thus, claims 1 and 6-11, which recite features not disclosed in the priority application are entitled only to the filing date of the instant application, which is March 10, 1998. See MPEP 201.22.

REASONS FOR ALLOWANCE

4. The following is an Examiner's statement of reasons for allowance:

Claims 1 and 8 have been amended supra in a manner which is consistent with the instant specification. Claims 7 and 10 have been replaced by new claims 12 and 13 in order to be consistent with the subject matter of claims 1 and 8. The Examiner's amendment was agreed to by Applicant in order to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In view of Applicant's amendment filed October 9, 1998 and the Examiner's amendment all outstanding grounds of rejection are withdrawn. The double

patenting rejections over U.S. Patent No. 5,726,873 (A, of record) were overcome by the Applicant's amendment because the invention of the '873 patent does not encompass feed particles with an anti-gut-peptide-antibody-comprising outer layer which is not fat encapsulated, a feature which is integral to the instant invention. The prior art of record does not teach or suggest the claimed invention.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

5. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Monday through Friday from 8:00 am to 4:30 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

December 4, 1998
F. Pierre VanderVegt, Ph.D.
Patent Examiner
Art Unit 1644

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM11/1207

BENNETT J.BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/037,690	03/10/98	007	VANDER VEGT, F 1644	12/07/98

First Named Applicant	35 USC 154(b) term ext. =	0 Days.
COOK,		

TITLE OF INVENTION: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 960296.94011	424-130.100	M33	UTILITY	NO	$1210.00	03/08/99

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or

B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue-Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to Issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

PART B—ISSUE FEE TRANSMITTAL

Complete and mail this form, together with applicable fees, to: **Box ISSUE FEE**
Assistant Commissioner for Patents
Washington, D.C. 20231

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

HM11/1207

BENNETT J. BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

Note: The certificate of mailing below can only be used for domestic mailings of the Issue Fee Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

Certificate of Mailing

I hereby certify that this Issue Fee Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above on the date indicated below.

Bennett J. Berson (Depositor's name)

(Signature)

February 26, 1999 (Date)

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/037,690	03/10/98	007	VANDER VEGT, F 1644	12/07/98

First Named Applicant: COOK,

35 USC 154(b) term ext. = 0 Days.

TITLE OF INVENTION: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 960296.94011	424-130.100	M33	UTILITY	NO	$1210.00	03/08/99

1. Change of correspondence address or indication of " Fee Address" (37 CFR 1.363). Use of PTO form(s) and Customer Number are recommended, but not required.

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" indication form PTO/SB/47) attached.

2. For printing on the patent front page, list, (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Quarles & Brady LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)
PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE
Wisconsin Alumni Research Foundation
(B) RESIDENCE: (CITY & STATE OR COUNTRY)
Madison, WI US

Please check the appropriate assignee category indicated below (will not be printed on the patent) :

☐ Individual ☒ corporation or other private group entity ☐ government

4a. The following fees are enclosed (make check payable to Commissioner of Patents and Trademarks):

☐ Issue Fee
☐ Advance Order - # of Copies

4b. The following fees or deficiency in these fees should be charged to:

DEPOSIT ACCOUNT NUMBER 17-0055
(ENCLOSE AN EXTRA COPY OF THIS FORM)

☒ Issue Fee
☒ Advance Order - # of Copies 10

The COMMISSIONER OF PATENTS AND TRADEMARKS IS requested to apply the Issue Fee to the application identified above.

(Authorized Signature) (Date) 2/26/99

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

03/04/1999 RTSEGA1 00000138 170055 09037690

01 FC:142 1210.00 CH
02 FC:561 30.00 CH

RECEIVED
MAR 11 1999
Technology Center 1600

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND FEES AND THIS FORM TO: Box Issue Fee, Assistant Commissioner for Patents, Washington D.C. 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE

EXPRESS MAIL LABEL NO. _____

PTO/SB/17 (1/98)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL

Patent fees are subject to annual revision on October 1. These are the fee effective November 10, 1998. Small Entity payments must be supported by a small entity statement otherwise large entity fee must be paid. See Forms PTD/SB/09-12

TOTAL AMOUNT OF PAYMENT | $ 1240.00

Complete if Known	
Application Number	09/037,690
Filing Date	03/10/98
First Named Inventor	Mark E. Cook
Group Art Unit	1644
Examiner Name	F. VanderVegt
Attorney Docket Number	960296.95297

OIPE MAR 0 3 1999 PATENT & TRADEMARK OFFICE

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady LLP

[ ] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17 [X] Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. [ ] Payment Enclosed: [ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fee effective 11/10/98)

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	760	201	380	Utility filing fee	
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	760	208	380	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)

2. CLAIMS

	Extra		Fee from below	Fee Paid
Total Claims	-20** =	X		=
Independent Claims	-3** =	X		=
Multiple Dependent Claims				=

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	09	Claims in excess of 20
102	78	202	39	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim
109	78	209	39	**Reissue independent claims over original patent
110	18	210	09	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)		Fee
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920	112	920	Requesting publication of SIR prior to Examiner action	
113	1,840	113	1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	380	216	190	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,380	218	690	Extension for reply within fourth month	
128	1,860	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,210	241	605	Petition to revive unintentionally abandoned application	
142	1,210	242	605	Utility issue fee (or reissue)	1210
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	760	246	380	Filing a submission after final rejection (37 CFR 1.129(a))	
149	760	249	380	For each additional invention to be examined (37 CFR 1.129(b))	

Other fee (specify) Advance order: 30

Other fee (specify): _____

SUBTOTAL (3) ($)1240.00

* Reduced by Basic Filing Fee Paid

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	Bennett J. Berson			Reg. Number	37,094
Signature		Date	February 28, 1999	Deposit Account User ID	

CIBMAD\182248

RECEIPT

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Signature and Deposit: December 15, 1998

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. Cook
Daria L. Jerome

Date: December 15, 1998

Serial No.: 09/037,690

Group Art Unit: 1644

Filed: 03/10/98

Examiner: F. VanderVegt

For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

File No.: 960296.94011
(now 960296.95297)

JAN 20 1999

REQUEST FOR CORRECTED FILING RECEIPT

Assistant Commissioner For Patents
Application Processing Division
Customers Correction Branch
Washington DC 20231

Dear Sir:

An error is noted in the Corrected Filing Receipt received in connection with the above-noted patent application.

The applicants had asked that the attorney docket number be updated so that the last five digits are 95297. Unfortunately, the last five digits were changed to 94297.

Please correct the attorney docket number so that it reads 960296.95297 as noted on the accompanying copy of the Corrected Filing Receipt.

Respectfully submitted,

Bennett J. Berson
Reg. No. 37,094
Attorney for Applicants
QUARLES & BRADY
P.O. Box 2113
Madison, WI 53701-2113
(608) 251-5000

QBMAD\176964

PTO-103X
(Rev. 7-93)

FILING RECEIPT

CORRECTED

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/037,690	03/10/98	1644	$1,002.00	960296.97297	0	10	4

5

BENNETT J.BERSON
QUARLES & BRADY
PO BOX 2113
MADISON WI 53701-2113

Receipt is acknowledged of this patent application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

MARK E. COOK, MADISON, WI; DARIA L. JEROME, FRAZEE, MN.

CONTINUING DATA AS CLAIMED BY APPLICANT-
THIS APPLN IS A CIP OF 08/684,785 07/22/96 PAT 5,725,873

FOREIGN FILING LICENSE GRANTED 03/27/98
TITLE
METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

PRELIMINARY CLASS: 424

DATA ENTRY BY: WILSON, PAMELLA TEAM: 12 DATE: 12/07/98

(see reverse)

EXPRESS MAIL LABEL NO. _____

PTO/SB/17 (1/98)
Appr for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL

DEC 21 1998

Patent fees are subject to annual revision on October 1.
These are the fees effective November 29, 1998.
Small Entity payments must be supported by a small entity statement
otherwise large entity fees must be paid, See Forms PTO/SB/09-12

TOTAL AMOUNT OF PAYMENT $

Complete If Known	
Application Number	09/037,690
Filing Date	03/10/98
First Named Inventor	Mark E. Cook
Group Art Unit	1644
Examiner Name	F. VanderVegt
Attorney Docket Number	960296.95297

METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady LLP

[X] Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

[ ] Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.311(b)

2. [ ] Payment Enclosed:

[ ] Check [ ] Money Order [ ] Other

FEE CALCULATION (fees effective 11/10/98)

1. FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	760	201	380	Utility filing fee	
106	310	206	155	Design filing fee	
107	480	207	240	Plant filing fee	
108	760	208	380	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($)

2. CLAIMS

	Extra		Fee from below	Fee Paid
Total Claims	-20**=	X	=	
Independent Claims	-3**=	X	=	
Multiple Dependent Claims				

** or number previously paid, if greater, For reissues see below

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	09	Claims in excess of 20
102	78	202	39	Independent claims in excess of 3
104	260	204	130	Multiple dependent claim
109	78	209	39	**Reissue independent claims over original patent
110	18	210	09	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	*920	112	*920	Requesting publication of SIR prior to Examiner action	
113	*1,840	113	*1,840	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	360	216	180	Extension for reply within second month	
117	870	217	435	Extension for reply within third month	
118	1,380	218	690	Extension for reply within fourth month	
128	1,860	228	925	Extension for reply within fifth month	
119	300	219	150	Notice of Appeal	
120	300	220	150	Filing a brief in support of an appeal	
121	260	221	130	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,210	241	505	Petition to revive unintentionally abandoned application	
142	1,210	242	505	Utility issue fee (or reissue)	
143	430	243	215	Design issue fee	
144	580	244	290	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	760	246	380	Filing a submission after final rejection (37 CFR 1.129(a))	
149	760	249	380	For each additional invention to be examined (37 CFR 1.129(b))	
Other fee (specify)					
Other fee (specify)					

SUBTOTAL (3) ($)

* Reduced by Basic Filing Fee Paid

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	Bennett J. Berson			Reg. Number	37,094
Signature		Date	December 21 1998	Deposit Account User ID	

DBMAD\176985

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark E. Cook Daria L. Jerome	Date: November 3, 2003
Patent No.: 5,919,451	Issued: July 6, 1999
Serial No.: 09/037,690	Group Art Unit: 1644
Filed: March 10, 1998	Examiner: F. Pierre VanderVegt
For: METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN	Docket No.: 960296.95297

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. §1.322(a)

Commissioner For Patents
P O Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby request that the attached Certificate of Correction be issued in conjunction with the above-noted patent.

A Certificate of Correction requesting inclusion of federal funding is enclosed.

A fee in the amount of $100.00 is believed due in connection with this Certificate. Please charge the fee to deposit account number 17-0055. Should the Office have any questions, please contact the undersigned directly.

Respectfully submitted,

Bennett J. Bersch
Reg. No. 37,094
Attorney for the Applicants
QUARLES & BRADY LLP
P.O. Box 2113
Madison, WI 53701-2113

TEL 608/251-5000
FAX 608/251-9166

QBMAD\366073.1

PTO/SB/44 (02-01)
Approved for use through 01/31/2004.
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

CR

NOV 13 2002

PATENT NO : 5,919,451

DATED : July 6, 1999

INVENTOR(S) : Mark E. Cook/Daria L. Jerome

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

~~In the Specification~~

Col. 1, Page 1, line 9, please delete the entire paragraph and insert therefor the following:

--This invention was made with United States government support awarded by the following agencies:

USDA 96-CRHR-0-6055

The United States has certain rights in this invention.--

MAILING ADDRESS OF SENDER: Bennett J Berson
Quarles & Brady LLP
P O Box 2113
Madison, WI 53701-2113

PATENT NO. 5,919,451

No. of additional copies

OIPE

NOV 0 6 2003

Express Mail No.

#12 S.S CofC

PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Burden Hour Statement: This information collection is estimated to take 12 minutes to complete. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 100.00

Complete If Known		
Application Number	09/037,690	5,919,451
Filing Date	03/10/1998	07/06/1999
First Named Inventor	Mark E. Cook	
Examiner Name	F. Pierre VanderVeat	
Art Unit	1644	
Attorney Docket No.	960296.95297	

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☑ Deposit Account:

Deposit Account Number: 17-0055

Deposit Account Name: Quarles & Brady LLP

The Director is authorized to: *(check all that apply)*

☑ Charge fee(s) indicated below ☑ Credit any overpayments

☑ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims	Fee from below	Fee Paid
Total Claims	-20** =	x	0.00
Independent Claims	-3** =	x	0.00
Multiple Dependent			

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) 1811 Certificate of Correction 100

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 100.00

Certificate of Correction
NOV 13 2003

SUBMITTED BY				(Complete if applicable)	
Name (Print/Type)	Bennett J. Person	Registration No. (Attorney/Agent)	37,094	Telephone	608/251-5000
Signature				Date	November 3, 2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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NOV 13 2003

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,919,451
DATED : July 6, 1999
INVENTOR(S) : Mark E. Cook and Daria L. Jerome

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1,
Line 9, please delete the entire paragraph and insert therefor the following:
-- This invention was made with United States government support awarded by the following agencies:
USDA 96-CRHR-0-6055
The United States has certain rights in this invention. --

Signed and Sealed this

Ninth Day of December, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

PATENT NUMBER

APPLICATION SERIAL NUMBER
09/037,690

APPLICANT'S NAME (PLEASE PRINT)
Cook et al

If REISSUE, ORIGINAL PATENT NUMBER

INTERNATIONAL CLASSIFICATION

A	61	K	39/395
A	23	J	3/12
A	23	J	1/06
A	23	K	1/16

ORIGINAL CLASSIFICATION

CLASS	SUBCLASS
424	130.1

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)			
424	157.1	158.1	442	
106	124.1			
426	89	140	657	
530	388.2			

GROUP ART UNIT: 1644

ASSISTANT EXAMINER (PLEASE STAMP OR PRINT FULL NAME)
F. Pierre VanderVegt

PRIMARY EXAMINER (PLEASE STAMP OR PRINT FULL NAME)
David A. Saunders

PTO 270 (REV. 5-91)

ISSUE CLASSIFICATION SLIP

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

1 7 8 10

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 1997

Application or Docket Number: 09/037690

CLAIMS AS FILED - PART I

	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
FOR		
BASIC FEE		
TOTAL CLAIMS	10 minus 20 =	* 0
INDEPENDENT CLAIMS	4 minus 3 =	* 1
MULTIPLE DEPENDENT CLAIM PRESENT		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE [ ] RATE	FEE	OR	OTHER THAN SMALL ENTITY RATE	FEE
	395.00	OR		790.00
x$11=		OR	x$22=	
x41=		OR	x82=	82.
+135=		OR	+270=	
TOTAL		OR	TOTAL	872.

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
x$11=		OR	x$22=	
x41=		OR	x82=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
x$11=		OR	x$22=	
x41=		OR	x82=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE	OR	RATE	ADDITIONAL FEE
x$11=		OR	x$22=	
x41=		OR	x82=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, 20(12), 2035-2039 (1994)

IMPROVED STABILITY OF LIPID COATED VITAMIN A IN ANIMAL FEED ADDITIVES

R.B.Albright (1) AND C.H.Kowarski (2) *

(1)Lambert-Kay div. of Carter-Wallace , Cranbury N.J.
(2)Temple University School of Pharmacy, Phila. Pa.

ABSTRACT

Lipids have been studied as methods of encapsulation, permeation enhancers, and as drug delivery systems. A lipid coating containing lecithin,cholesterol and functionalized stearyls was utilized in this study to inhibit the mineral catalyzed Vitamin A degradation in a dry flowable animal feed additive. Results indicate much improved stability.

INTRODUCTION

Vitamin A is very susceptable to oxidation, heat, light, moisture and metal catalysis. (1) (2). Oxidation and hydrolysis are accelerated at high temperatures. Solid formulations are as unstable as liquid Vitamin A products due to the large surface area present for reaction (3). In feed mixtures, the presence of water, peroxides, minerals and peroxidized unsaturated fats all add to the instability of Vitamin A.

Mineral mixtures ordinarily are used to supply calcium, phosphorus and trace minerals to animals and can catalyze the oxidative degradation of Vitamin A.

Vitamin A undergoes both pseudo-zero and first order reactions in liquid media (2). Carstensen has found a log-linear ratio between the first order rate constant and water-vapor pressure (6). Controlling the humidity is one method of improving Vitamin A stability in the solid matrix. Vitamin A solid preparations have shown increased stability when Vitamin A was encapsulated in gelatin (2).

The purpose of this study is to investigate the use of lipid coatings on a powder containing absorbed Vitamin A. The formulation is specifically a vitamin/mineral feed supplement for use in animal nutrition.

By coating a vitamin A dispersion in the components of a lipid bilayer, two results may be realized:

1. Stability from mineral catalyzed degradation.
   The lipid bilayer may halt the catalytic decomposition reaction by physically separating Vitamin A from the mineral components.

* To whom inquiries should be addressed

2. Stability from hydrolytic degradation. If water permeates the bilayer it may be encapsulated by so-called liposome formation and not be available to interact with vitamin A.

MATERIALS AND METHODS

The following materials were used in this study: Vitamin A Palmitate 1,000,000 I.U./ gram was a gift of Hoffman-LaRoche. Lecithin (dry) was food grade and purchased from Central Soya (Decatur, Il.). Stearylamine was purchased from Aldrich Chemical and Cholesterol U.S.P. , Stearic Acid N.F. and Stearyl Alcohol N.F. were purchased from Ruger Chemical. The Lambert-Kay division of Carter-Wallace gave the vitamin/mineral premix used in this study.

The vitamin/mineral premix used in the study is a nutritionally complete mixture of vitamins, amino acids and the following minerals: calcium,phosphorus, potassium, sodium, magnesium, iron, copper, zinc, manganese, and cobalt, as pharmaceutically acceptable salts.

Formulations were prepared in a 5 Kg. Hobart blender at ambient temperature. The Vitamin A Palmitate was adsorbed onto a dry carrier such as Potassium Phosphate Monobasic (Anhydrous). The lipid composition was then melted in a seperate vessel (heat) and poured onto the agitating Vitamin A coated carrier. After agitation and cooling (30 minutes), the vitamin/mineral premix was added. Agitation continued for 15 minutes . Total mixing time was 45 minutes. The lab prep was done at ambient temperature and relative humidity. No requirements for an inert atmosphere were utilized.

ANALYTICAL METHOD

Vitamin A stability of the powder was analyzed by HPLC using a 0.4 X 30 cm. Porasil column at 313 nm. using a mobile phase of 98:2 Isooctane : Ethyl Ether . Stock and working solutions of Vitamin A palmitate were prepared in hexane and a calibration curve was prepared. Sample preparation consisted of weighing 50-60 mg of sample into 5 ml DMSO. Extraction of the Vitamin A was done with heat and agitation. 25 ml of hexane was added and agitation and centrifugation followed. 5 ml of the supernatant was pipetted into a 50 ml volumetric flask and was diluted with hexane. The injection volume was 7 microliters.

STABILITY TESTING

Formulations 1 through 4 were analyzed in accordance with the preceeding HPLC method. Storage stability samples of the formulations were analyzed initially, at 1 month, 3 months and 6 months. The samples were stored in the following conditions: ambient temperature (approx.25 degrees), and 37 degrees centigrade in dark cabinets or ovens. Analyses were run in duplicate and averaged for data analysis.

The finished formulas were split into 300 gram amber tinted polystyrene wide mouth bottles, filled to the top and sealed with a torque of 10 to 20 foot-pounds and stored at the indicated conditions. Initial analysis was done to verify initial concentration and recovery. Each bottle was considered a sample volume and duplicate weighings were done for analysis.

Samples were analyzed by HPLC as previously indicated. The results were averaged and normalized to percent of initial assay (100%) (Table 2). All samples were analyzed for moisture content by Karl Fischer method. In all samples, moisture content was below 1 %.

DISCUSSION OF RESULTS

Table 3 is a comparision of zero order and (pseudo) first order constants and their R-squared values. These results were developed from the stability data of Table 2. Once the

TABLE 1
Formulations of Lipid Coated Powders

FORMULATIONS NUMBER:	1.	2.	3.	4.
LECITHIN	-	1.69	1.69	1.69
CHOLESTEROL	-	0.83	0.83	0.83
STEARIC ACID	-	-	0.26	-
STEARYLAMINE	-	0.26	-	-
STEARYL ALCOHOL	-	-	-	0.28
VITAMIN A PALMITATE	0.61	0.61	0.61	0.61
POTASSIUM PHOSPHATE MONOBASIC (ANH.)	57.66	54.98	54.98	54.96
VIT./MINERAL PREMIX	41.71	41.61	41.61	41.61

TABLE 2
Storage Stability Results
% OF Initial Vitamin A Concentration

FORMULA:	1 (CONTROL)		2		3		4	
TEMPERATURE:	R.T.	37	R.T.	37	RT	37	R.T.	37
1 MONTH	85.2	69.0	92.2	75.0	102	92.1	101.1	90.9
3 MONTHS	93.6	83.0	96.1	34.7	93.9	74.6	100.3	77.9
6 MONTHS	43.3	42.0	75.0	26.0	90.2	56.1	97.0	60.1

R.T. is room temperature
37 is 37 degrees centigrade

TABLE 3

Comparision Of Slopes and Regression Coefficients
Of Zero Order and Pseudo-First Order Degradation Profiles

FORMULATION	TEMP	ZERO ORDER		PSEUDO-FIRST ORDER	
		SLOPE	R	SLOPE	R
1 (CONTROL)	R.T.	-5.23	0.7	-10.61	0.61
	37	-11.13	0.89	-11.27	0.97
2	R.T.	-4.16	0.93	-7.51	0.58
	37	-22.12	0.99	-17.92	0.89
3	R.T	-1.95	0.88	-2.31	0.59
	37	-7.38	0.99	-9.61	0.82
4	R.T	-0.56	0.72	-0.50	0.25
	37	-8.60	0.99	-0.86	0.64

TABLE 4
Summary Of Lipid Formulae Reaction Kinetics

PRODUCT	TEMP	REACTION ORDER	%LOSS/DAY	VITAMIN A LOSS/DAY
1 (CONTROL)	R.T.	1	0.172	258
	37 DEGREES	1	0.366	549
2	R.T.	0	0.137	205.5
	37 DEGREES	0	0.727	1090.5
3	R.T.	0	0.064	96.0
	37 DEGREES	0	0.243	364.5
4	R.T.	0	0.019	28.5
	37 DEGREES	0	0.217	325.5

Vitamin A loss per day is based on a normalized initial dose of 150,000 I.U.

lipid coating is applied to the Vitamin A powder, it is interesting to note that the reaction order seems top shift from (pseudo) first order to zero order. This shift is most obvious in the 37 degree data. This may indicate that the decomposition pathway may have changed. This will be the subject of future investigation.

The evaluated temperature data in all cases indicates a substantial increase in degradation of 37 degrees over room temperature for each system. This is due to the low melting range of the lipid coating. In all cases the lipid coating begins its phase transition at 35 degrees. This must be taken into consideration for purposes of commercial utility.

The addition of the lipid coatings to a dispersion of Vitamin A powders definitely increases stability at room temperature (TABLE 4). The decomposition of Vitamin A is retarded in each experimental system as follows:

EXPERIMENT	SYSTEM	FACTOR OF STABILITY IMPROVEMENT
1	CONTROL	1
2	LECITHIN/CHOLESTEROL/ STEARYLAMINE	2.63
3	LECITHIN/CHOLESTEROL/ STEARIC ACID	5.55
4	LECITHIN/CHOLESTEROL/ STEARYL ALCOHOL	20.0

This data indicates that a lipid coating deposited on the substrate containing absorbed Vitamin A retards degradation of the vitamin while in the presence of minerals which would otherwise catalyze degradation.

REFERENCES

1.Harris, Robert , The Vitamins , 2nd Edition Volume 1 Academic Press NY 1967 p.245

2. Connors, K.A., Amidon, G.L., and Kennon, L., Chemical Stability of Pharmaceuticals, John Wiley 1979 p.327

3.Buhler V. Vandemecum for Vitamin Formulations , Wissen Schaftliche, Verlagegese ll Shaft. mb H Stuttgart (1988)

4. Halverson A.W. and Hendrick C.M., Poultry Sci. 34:355 (1955)

5 Carstensen, J.T. J.Pharm. Sci. 53:839 (1964)

US005919451A

United States Patent [19]

Cook et al.

[11] Patent Number: 5,919,451

[45] Date of Patent: Jul. 6, 1999

[54] **METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN**

[75] Inventors: **Mark E. Cook**, Madison, Wis.; **Darla L. Jerome**, Frazee, Minn.

[73] Assignee: **Wisconsin Alumni Research Foundation**, Madison, Wis.

[21] Appl. No.: **09/037,690**

[22] Filed: **Mar. 10, 1998**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/684,785, Jul. 22, 1996, Pat. No. 5,725,873.

[51] **Int. Cl.**[6] **A61K 39/395**; A23J 3/12; A23J 1/06; A23K 1/16

[52] **U.S. Cl.** **424/130.1**; 424/157.1; 424/158.1; 424/442; 106/124.1; 426/89; 426/140; 426/657; 530/388.2

[58] **Field of Search** 424/442, 283.1, 424/130.1, 157.1, 158.1; 106/147.3, 148.1, 243; 426/89, 92, 140, 657; 530/388.24, 388.85, 389.2

[56] **References Cited**

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3,119,691	1/1964	Ludington et al.	99/2
4,357,272	11/1982	Polson	260/112
4,550,019	10/1985	Polson	424/85
4,748,018	5/1988	Stolle et al.	424/87
5,080,895	1/1992	Tokoro	424/85.8
5,428,072	6/1995	Cook et al.	514/460
5,725,873	3/1998	Cook et al.	424/442

FOREIGN PATENT DOCUMENTS

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OTHER PUBLICATIONS

Albright, RB et al. Drug. Dev. Ind. Pharm. 20(12):2035–2039, Jul. 1994.

Primary Examiner—David Saunders
Assistant Examiner—F. Pierre VanderVegt
Attorney, Agent, or Firm—Quarles & Brady LLP

[57] **ABSTRACT**

A method of improving the efficiency of an animal to convert feed into desirable body tissue involves feeding the animal feed particles having an inner core of nutrients and an outer layer containing a conjugated fatty acid or an antibody that can protect the animal from contacting diseases that can adversely affect the animal's ability to grow or efficiently convert its feed into body tissue.

7 Claims, No Drawings

METHOD OF IMPROVING THE GROWTH OR THE EFFICIENCY OF FEED CONVERSION OF AN ANIMAL AND COMPOSITIONS FOR USE THEREIN

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part application of application No. 08/684,785, filed Jul. 22, 1996, now U.S. Pat. No. 5,725,873, issued Mar. 10, 1998.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

BACKGROUND OF THE INVENTION

The present invention relates generally to the feeding of animals. More particularly, it relates to a method of improving the animal's growth or the efficiency of the animal to convert its feed into desirable body tissue (e.g. muscle) and compositions for use in the method.

It is known that healthy, disease-free animals grow faster or are more able to convert their feed efficiently into body tissue than sick or immune-challenged animals. Obviously, faster growth or a more efficient conversion of feed into desirable body tissue in an animal is both economically and ecologically important, especially in animals raised for food. For this, and other reasons, it is desirable to prevent animals from contacting diseases.

One approach to keeping animals healthy is to give the animals antibiotics. However, that approach is not desirable for animals raised for food because there can be antibiotic residues in the food.

Another approach to keeping animals healthy is to immunize the animals. This can be done by vaccinating the animals against specific diseases to produce an active immunization or by administering to the animals antibodies to produce a passive immunization.

In U.S. Pat. Nos. 4,748,018 and 5,080,895, methods are disclosed for passively immunizing animals against intestinal diseases which could interfere with the animal's efficient conversion of feed. The patented methods basically comprise orally administering to said animals effective amounts of egg-derived materials containing avian antibodies which are obtained by immunizing egg-laying hens with specific antigens which will produce such antibodies, and obtaining the antibody containing material from eggs laid by the hen. In both patents, the antibody containing egg materials are reduced to powders and fed to the animals to be passively immunized.

BRIEF SUMMARY OF THE INVENTION

It is the primary object of the present invention to disclose a novel method to improve the animals growth or the efficiency of the animal to convert its feed into desirable body tissue.

Another object of the invention is to disclose an animal feed for animals for use in the inventive method.

The method of the present invention to improve the animals growth or the efficiency of the animal to convert its feed into desirable body tissue comprises orally administering to said animal feed particles having an inner core comprising primarily non-fat nutrients and, on an outer surface of the inner core, a safe and effective amount of an antibody that help protect the animal from disease or other antigens that can adversely affect the animal's growth or the efficiency of the animal to convert feed into desirable body tissue. The particles can alternatively be coated with another compound that improves the efficiency of the animal to convert feed into desirable body tissue.

The compositions of the present invention are animal feed particles having an inner core comprised of nutrients, and, on an outer surface of the inner core, a compound that improves the efficiency of the animal to convert feed into desirable body tissue.

The compositions of the present invention are conveniently made by first forming a nutrient mixture to produce an inner core, and then depositing the compound on the outer surface of the core. Surprisingly, an antibody on the outer surface retains immunological activity and is not destroyed by antibody destroying factors, such as environmental conditions and intestinal proteases, even if the antibody is simply applied to the exterior of the pellet core without encapsulation in a protective fat layer.

In a preferred embodiment of the invention, antibodies are provided in solution or suspension in an aqueous or lipid carrier, although the antibodies can be applied directly to the pellet core without a carrier as, for example, a powder. The antibodies can be, but need not be, encapsulated in the lipid. The antibodies are obtained from the egg of a hen which has been injected with an antigen that results in the production by the hen of those antibodies.

Compositions of the present invention are superior to previously known animal feeds in which antibody-containing powders were mixed with nutrients, including fat, and then granulated or extruded, because the antibody-containing layer in the method of the present invention is applied to the core after the pelletization, extrusion, granulation or expansion process. As a result the antibodies in the outer layer of the compositions of the present invention are not degraded by elevated temperatures that can arise during pelletization, granulation, extrusion or expansion processes. The compositions of the present invention are also superior to prior art feeds. If the antibodies are mixed into an outer layer of fat, the fat helps protect the antibodies from stomach acid and intestinal enzymes. If the antibodies are not encapsulated in fat, they can be immediately released at high concentration into the gastrointestinal tract of the consuming animal and are not degraded upon ingestion.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Not applicable.

DETAILED DESCRIPTION OF THE INVENTION

In the preferred embodiment of the present invention, the animal feed particles comprise an extruded inner core which contains primarily the desired non-fat materials, such as proteins and carbohydrates, and an outer layer of a compound that improves the efficiency of the animal to convert feed into desirable body tissue. The compound is preferably an antibody which can be optionally encapsulated in a lipid layer. Another compound that can be provided on the outer surface is a fatty acid that improves feed conversion efficiency. A preferred fatty acid is an 18-carbon conjugated diene. A most preferred fatty acid is conjugated linoleic acid (CLA). The outer layer also can contain other ingredients, such as oil-soluble vitamins and the inner core can, of course, also contain fat, if desired.

In the preferred practice of the method of invention, the animal feed is orally fed to the animal in an amount which will passively immunize the animal or otherwise enhance the efficiency of feed conversion by the animal.

The antibodies for use in the present invention are those which can alter physiological processes that adversely affect growth and feed efficiency. They can be antibodies that are against diseases or specific endogenous regulators of food intake and gastrointestinal motility. The antibodies are preferably derived from the eggs of hens which have been previously immunized to produce those antibodies as described in U.S. Pat. Nos. 4,748,018 or 5,080,895. Especially preferred as the antibody-containing material are spray dried egg yolks and whole eggs. However, other non-egg derived antibody-containing materials may be used.

The free CLA isomers have been previously isolated from fricd meats and described as anticarcinogens by Y. L. Ha et al., in Carcinogenesis 8(12):1881–1887 (1987). Since then, they have been found in some processed cheese products. Y. L. Ha, et al., J. Agric Food Chem. 37(1):75–81 (1987).

The free acid forms of the CLA may be prepared by isomerizng linoleic acid. The non-toxic salts of the free CLA may be made by reacting the free acids with a non-toxic base. Natural CLA may also be prepared from linoleic acid by the action of delta 12-cis, delta 11-transisomerase from a harmless microorganism such as the rumen bacterium *butyrivibrio fibrisolvens*. Harmless microorganisms in the intestinal tracts of rats and other monogastric animals may also convert linoleic acid to CLA (Chin, S. F. et al., FASEB J. v. 6, abstract #2665 (1992).

The CLA obtained by the practice of the described methods contains one or more of the 9,11-octadecadienoic acids and/or the 10,12-octadecadienoic acids and active isomers thereof. It may be free or bound chemically through ester linkages. The CLA is heat stable and can be used as is, or dried and powdered. The CLA is readily converted into a non-toxic salt, such as the sodium or potassium salt, by reacting chemically equivalent amounts of the free acid with an alkali hydroxide at a pH of about 8 to 9.

CLA can be a mixture of isomers of 9,11- and 10,12-octadecadienoic acid (**c9, c11**; **c9, t11**; **t9, c11**; **t9, t11**; **c10, c12**; **t10, c12**; **c10, t12**; and **t10, t12**) that would form from isomerization of **c9, c12**-octadecadienoic acid. As a result of the isomerization, only four isomers (**c9, c11**; **c9, t11**; **t10, c12**; and **c10, c12**) would be expected. However, of the four isomers, **c9, t11**- and **t10, c12** isomers are predominantly produced during the autoxidation or alkali-isomerization of **c9, c12** -linoleic acid due to the co-planar characteristics of carbon atoms around a conjugated double-bond and spatial conflict of the resonance radical. The remaining two c,c-isomers are minor contributors.

The relatively higher distribution of the t,t-isomers of 9,11- or 10,12-octadecadienoic acid apparently results from the further stabilization of **c9, t11**- or **t10, c12**-geometric isomers, which is thermodynamically preferred, during an extended processing time or long aging period. Additionally, the t,t isomer of 9,11- or 10,12-octadecadienoic acid that was predominantly formed during the isomerization of linoleic acid geometrical isomers (**t9, t12**-, **c9, t12**- and **t9, c12**-octadecadienoic acid) may influence the final ratio of the isomers or the final CLA content in the samples.

Linoleic acid geometrical isomers also influence the distribution of minor contributors (c,c-isomers of 9,11- and 10,12-, **t9, c11**- and **c11, t12**-octadecadienoic acids). The 11,1,3-isomer might be produced as a minor product from **c9, c12**-octadecadienoic acid or from its isomeric forms during processing.

The preferred inner core for the animal feed particles is an extrusion which contains a mixture of nutrients, such as grains, with or without added sugars, carbohydrates and/or proteins. The core will normally contain less than the desired total amount of the dietary fat for the animal because of the fat in the outer layer.

The fat for use in the outer layer can be any fat or lipid, which can be readily mixed with the antibody containing material to form a mixture, which contains the antibody therein and which can be readily sprayed or otherwise coated on the outer surface of the core. The antibody need not be directly on the surface of the inner core. Rather, one or more intermediate layers, comprising, for example, a binding agent, can be provided between the antibody and the core. Especially preferred are those fats which are solid at ambient temperatures and which will protect the antibodies from adverse environmental conditions and intestinal enzymes. Especially preferred as the fat is a mixture of tallow and CLA which increases feed efficiency.

Representative of other fats that can be used are the following:

Lard
Yellow Grease
Poultry Fat
Spent Restaurant Oil
Animal Oils
Vegetable Oils
Fish Oils
Oil Derivatives, i.e. lecithin
and
Mixtures thereof.

The practice of the present invention is further illustrated by the following examples:

EXAMPLE 1

Preparation Of Antibodies

An antigen, such as cholecystokinin peptide which produces cholecystokinin (CCK) antibodies, is injected intramuscularly into mature hens at a dose of about 50 μg to 1000 μg with a water-in-oil emulsion adjuvant. Samples of the whole eggs or yolks of eggs from the hens are assayed by known methods for CCK antibody content. When the CCK antibody titer reaches a maximum level, the whole eggs or yolks of eggs are collected and pooled, homogenized and spray dried to obtain a powder.

EXAMPLE 2

Preparation Of Animal Feed Particles With Outer Layer Of Fat Containing Antibodies

A CCK antibody-containing powder made by the process of Example 1 is mixed with tallow to form a blend in which the powder is substantially encapsulated by the fat. The fat mixture is then spray coated upon inner cores made by the pelletization, the granulation, the extrusion or the expansion of a plasticized mixture of nutrients, including carbohydrate, protein and water. The resulting animal feed particles have an inner core of nutrients and an outer layer of fat containing CCK antibodies.

EXAMPLE 3

Animal Feeding Test

Ducks are fed the animal feed of Example 2 and their biological responses are determined. It is found that the

ducks receiving the animal feed of Example 2 demonstrate an improved body weight gain and a more efficient rate of feed conversion than control ducks.

Table 1 shows the results obtained in 14 day old ducks fed a control feed and an otherwise identical feed (BRAVO) having an outer antibody-containing layer.

TABLE 1

ABOVE BODY WEIGHT SUMMARY			
TREATMENT	14 day weight	27 day weight	14–27 day gain
Control	0.66 kg	2.03 kg	1.37 kg
Bravo	0.63 kg	1.96 kg	1.33 kg
TREATMENT	39 day weight	14–39 day gain	
Control	3.15 kg	2.49 kg	
Bravo	3.23 kg	2.60 kg	
FEED CONVERSION DATA			
TREATMENT	14–27 feed/bird	0–27 feed/bw*	14–17 feed/gain
Control	2.50 kg	0.858 kg	1.826 kg
Bravo	2.34 kg	0.541 kg	1.76 kg
TREATMENT	14–39 feed/bird	0–39 feed/bw*	14–39 feed/gain
Control	5.349 kg	0.781 kg	2.15 kg
Bravo	4.930 kg	0.695 kg	1.90 kg

*bw = body weight

EXAMPLE 4

A CCK antibody-containing powder made by the process of Example 1 were mixed with tallow to form a blend in which the powder was substantially encapsulated by the fat. The fat mixture was then spray coated upon the inner cores, as described in Example 2, at the indicated antibody levels.

Chickens were fed the animal feed and their biological responses were determined. Table 2 shows the results obtained in chickens fed the coated feed pellets (crumbles) for three weeks. Also shown are the results obtained when chickens were fed a standard feed mash containing the indicated amounts of the anti-CCK antibody.

In the course of the trial, both the rate of body gain and the feed efficiency were markedly higher in chickens fed the antibody-coated pellets than in those fed antibody-containing mash. Surprisingly, a superior increase is observed (relative to control feed) when the antibody is provided on pellets than as a component of mash.

TABLE 2

Treatment	Week 1 Body Wt	Week 0–1 Body Wt Gain	Feed/Bird 0–1 Consumed	Feed/Body Wt	Feed/Body Wt Gain
Week 1 (Mash)					
Control	132	93	124	0.938	1.344
0.075* Bravo	136	97	132	0.969	1.368
0.25 Bravo	138	98	131	0.947	1.338
0.75 Bravo	127	87	125	0.984	1.442

TABLE 2-continued

Treatment	Week 1 Body Wt	Week 0–1 Body Wt Gain	Feed/Bird 0–1 Consumed	Feed/Body Wt	Feed/Body Wt Gain
Week 2 (Crumbles)					
Control	152	112	143	0.942	1.287
0.075 Bravo	149	108	156	1.049	1.450
0.25 Bravo	155	114	141	0.969	1.315
0.75 Bravo	147	107	137	0.928	1.273
Week 2 (Mash)					
Control	311	272	384	1.237	1.421
0.075 Bravo	329	290	400	1.218	1.386
0.25 Bravo	323	283	396	1.226	1.401
0.75 Bravo	291	251	353	1.244	1.451
Week 2 (Crumbles)					
Control	366	325	477	1.243	1.390
0.075 Bravo	358	317	457	1.278	1.444
0.25 Bravo	358	317	470	1.314	1.485
0.75 Bravo	352	313	413	1.174	1.324
Week 3 (Mash)					
Control	624	584	823	1.316	1.406
0.075 Bravo	635	595	845	1.334	1.423
0.25 Bravo	608	568	835	1.375	1.473
0.75 Bravo	569	529	787	1.382	1.488
Week 3 (Crumbles)					
Control	683	642	936	1.373	1.461
0.075 Bravo	697	656	956	1.372	1.457
0.25 Bravo	699	659	971	1.395	1.482
0.75 Bravo	687	648	893	1.299	1.379

*grams of anti-CCK egg yolk per kilogram of feed.

EXAMPLE 5

Ducks were fed a pelleted diet on which either 0.5% corn oil (control) or 0.5% conjugated linoleic acid was sprayed on the outer surface of the pellets. The coated pellets were fed to 14 day old ducks for 13 days. Feed conversion (feed consumed per amount of gain) was determined from 14 to 27 days and 29 to 39 days of age.

TABLE 3

Treatment	14–27 day conversion	29–39 day conversion
Control	1.82	2.38
CLA	1.79	2.14

Feeding CLA from 14 to 27 days of age reduced feed conversion (pounds of feed per pound of gain). The effects of feeding pellets coated with CLA continued to have an effect even for the period between 29 to 39 days of age.

It will be apparent to those skilled in the art that the present invention can be used to prepare the animal feed for a wide variety of food animals or pets, including without limitation, ducks, chickens and turkeys.

It also will be readily apparent to those skilled in the art that a large number of changes and modifications can be made without departing from the spirit and scope of the present invention. Therefore, it is intended that the invention only be limited by the claims which follow.

We claim:

1. A method to improve the growth of an animal or the efficiency of an animal to convert feed into desired body tissue, said method comprising feeding an animal an effective amount of animal feed particles comprising an inner core of nutrients and having an outer surface, and a layer

consisting essentially of unencapsulated antibodies on the outer surface of the inner core,

said antibodies being antibodies that can passively immunize the animal against the adverse effects of an endogenous gut peptide which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue, wherein the method achieves superior growth or feed conversion than a second method wherein a comparable amount of the antibody is fed to the animal in an unpelleted form.

2. A method of claim **1** in which the antibodies are derived from a chicken egg.

3. A method of claim **1** in which the antibody is anti-cholecystokinin antibody.

4. A method to improve the growth of an animal or the efficiency of an animal to convert feed into desired body tissue, said method comprising feeding an animal an effective amount of animal feed particles comprising an inner core of nutrients and having an outer surface, and a layer consisting essentially of unencapsulated antibodies and conjugated linoleic acid on the outer surface of the inner core, said antibodies being antibodies that can passively immunize the animal against the adverse effects of an endogenous gut peptide which could reduce the animal's ability to grow or to efficiently convert its feed into desirable body tissue, wherein the method achieves superior growth or feed conversion than a second method wherein the antibody is fed to the animal in an unpelleted form.

5. A particulate animal feed comprising an inner core of nutrients, the core having an outer surface, and a layer consisting essentially of at least one unencapsulated antibody to an endogenous gut peptide on the outer surface of the inner core.

6. A particulate animal feed as claimed in claim **5** wherein the antibodies are anti-cholecystokinin antibodies.

7. A particulate animal feed comprising an inner core of nutrients, the core having an outer surface, and a layer consisting essentially of conjugated linoleic acid and at least one unencapsulated antibody to an endogenous gut peptide on the outer surface of the inner core.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,919,451
DATED : July 6, 1999
INVENTOR(S) : Mark E. Cook and Daria L. Jerome

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1,
Line 9, please delete the entire paragraph and insert therefor the following:
-- This invention was made with United States government support awarded by the following agencies:
USDA 96-CRHR-0-6055
The United States has certain rights in this invention. --

Signed and Sealed this

Ninth Day of December, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office